2024

MSDS

Minimum Service Delivery Standards for HOSPITALS

Punjab Healthcare Commission

Striving for Quality Healthcare in Punjab

پنجاب ہیلتھ کیئر کمیشن
PUNJAB HEALTHCARE COMMISSION
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FOREWORD

The Punjab Healthcare Commission (PHC) is an autonomous health regulatory body established under the PHC Act 2010 for improving the quality of patient care through standardization of healthcare service delivery in Punjab. Under this mandate, the PHC developed and enforced the Minimum Service Delivery Standards (MSDS) and associated Indicators for Hospitals to introduce a culture of Clinical Governance grounded in the principles of responsibility and accountability. The intent of enforcing the service delivery standards is to subsequently improve the quality, safety and efficiency of healthcare service delivery.

The standards in the MSDS, a product of extensive consultations with international and local health experts, and relevant stakeholders, were reviewed and endorsed by the Technical Advisory Committee (TAC), and approved by the Board of Commissioners (BOC) of the PHC and notified by the Government of Punjab in 23rd October 2012. A total of 30 Standards and 162 indicators in the MSDS cover all the vital areas of healthcare service delivery, including the clinical and management aspects, covering inter-alia, Care of Patients and Management of Medication to Continuous Quality Improvement, Infection Control and Information Management Systems. Ensuring that the MSDS is practically applicable in the local context, each indicator is accompanied by a scoring matrix to facilitate implementation and assess compliance of Standards.

Initially, it was perceived that the MSDS would be applicable to all hospitals, including, the mega tertiary care hospitals in the larger urban cities as well as the medium and smaller size healthcare establishments (HCEs) in the peripheral districts providing varying scope of indoor services and having limited bed capacity.

The enforcement experience however, revealed that separate set of standards would be needed for the hospitals having less than 50 beds and this MSDS would be implemented at hospitals having more than 50 beds, the category I HCEs. It was in that background that the PHC embarked upon developing dedicated set of standards for the hospitals having capacity of less than 50 indoor beds and finalized MSDS for Category II HCEs that was notified by the Government of Punjab in 18th October 2014.

This MSDS was later, further modified into four sets to match the capacity and scope of work of the HCEs, sub categorized into; category II A (31 to 49 beds), category II B (16 to 30 beds), category II C (up to 15 beds) and the Rural Health Centres (RHCs), having up to 20 beds and providing basic medical, surgical and diagnostic services. Based on the implementation experience, it was observed that in the current format, some of the indicators are prone to subjective assessment and scoring.

The PHC therefore, decided to review the MSDS for category I HCEs, to make it implementation and assessment friendly through addressing the element of subjectivity and at the same time ensuring that the quality of care and patient safety is not compromised. The document in hand has accordingly, been modified by the PHC team of Clinical Governance and Organizational Standards as revised edition of MSDS for category I HCEs seeking professional inputs from the assessment teams as well as the implementers. It incorporates the intent statement highlighting the importance and requirement of each standard besides enlisting the compliance requirements and assessment methodology for each indicator to make the scoring process more objective.

I would like to thank the members from the inspection team and all the focal persons from the HCEs who made extremely beneficial suggestions aa stakeholders for making the MSDS more explicit and user friendly. My special appreciation also goes to the Clinical Governance and Organizational Standards team of the PHC under the leadership of the Chief Executive Officer for their diligence and hard work in achieving this crucial milestone of finalizing the revised edition of MSDS. Lastly, I am grateful to my fellow Commissioners of the Board for their strategic guidance towards the functioning of the PHC and support in the development of this document.

I sincerely hope that the revised edition of the MSDS, would mark an important step towards achieving its purpose of ensuring patient safety through providing quality healthcare services to the people of Punjab.

Chairperson
Board of Commissioners
Punjab Healthcare Commission

List of Acronyms and Abbreviations

AAC	Access, Assessment and Continuity of care
ASA	American Society of Anaesthesiologists
COP	Care of Patients
CQI	Continuous Quality Improvement
DFID	Department for International Development
FGD	Focus Group Discussion
FMS	Facility Management and Safety
HIC	Hospital Infection Control
HRM	Human Resource Management
ICU	Intensive Care Unit
IMS	Information Management Systems
IND	Indicator
JCAHO	Joint Commission for Accreditation of Healthcare Organizations
JCI	Joint Commission International
KCl	Potassium Chloride
MOM	Management of Medication
MSDS	Minimum Service Delivery Standards
OH&S	Occupational Health and Safety
PHC	Punjab Healthcare Commission
PNAC	Pakistan National Accreditation Council
PNRA	Pakistan Nuclear Regulatory Authority
PRE	Patient Rights and Education
QA	Quality Assurance
QHA	Quality Holistic Accreditation
ROM	Responsibilities of Management
SEPP	Society of Emergency Physicians Pakistan
SOPs	Standard Operating Procedures
TAC	Technical Advisory Committee
TAMA	Technical Assistance Management Agency

01

Introduction

1 - Introduction

The Government of the Punjab, charged with the role of providing quality services to its citizens and ensuring patient safety, promulgated the Punjab Healthcare Commission Act 2010 to establish the Punjab Healthcare Commission (PHC) to regulate the healthcare service deliver, both in the public and private sector. The vision of the PHC is 'to promote high quality and safe healthcare delivery for all' and the mission is 'to continually raise standards of healthcare delivery' throughout Punjab. A reputable team of national and international health experts collaborated to develop and finalize the minimum service standards (MSDS) for hospitals in 2012. The standards are largely based on the healthcare standards prescribed by the Joint Commission International (JCI) that provides 1500+ Indicators while Australian, New Zealand, Indian, UK, and Canadian standards consulted as part of literature review while developing MSDS. The standards and indicators were however, considerably reduced in number, while adapting their scope to suit the local context to ensure a realistic approach considering the ground realities in the foundation years for their enforcement by the PHC.

Prior to presenting the MSDS for review and endorsement by the TAC for approval by the BOC, the standards and indicators included were scrutinized by a wider group of professionals, in a Focus Group Discussion (FGD) held on 31st May 2011. Participants included renowned medical practitioners from key public and private hospitals who have also been actively involved in the PHC Stakeholder Workshop held earlier in January 2011 and in the Licensing, Accreditation and Regulation Workshop in March 2011. The objective of the FGDs and a series of consultative meetings with relevant stakeholders and health professionals was to ensure their involvement and engagement with the MSDS development process by the PHC.

The PHC's Technical Advisory Committee (TAC) reviewed, amended and endorsed the MSDS in August 2012 prior to approval by the Board of Commissioners and notification by the Government. Minimum Service Delivery Standards (MSDS) and indicators included the fundamental elements that should be present in all healthcare establishments in order to deliver safe health services. They MSDS developed by indigenous experts working in the field of healthcare provision and management covered; Patient and Organization centered standards and included guidance on the assessment and scoring process.

The MSDS comprising 30 "Foundation Standards" and 162 associated Indicators notified by the PHC are driven by an evidence-based research and designed to promote a safe environment providing risk management strategies. The Healthcare Standards and Indicators were however, considered dynamic, in view of the constant development of healthcare treatments, practices and protocols and to benefit both patients and healthcare establishments. It was anticipated that the range and scope of standards and their indicators will be expanded in collaboration with the Leaders and professionals in the Health Sector, the regulatory Councils, research and training institutions, the Boards and the professional Associations.

1.1 Service Delivery Standards – Historical Perspective

Quality standards for hospitals and other medical facilities were first introduced in the USA in 1917. After World War II, increased world trade in manufactured goods led to the creation of the International Standards Organization (ISO) in 1947. Building on successes in Japan, Total Quality Management (TQM) and Continuous Quality Improvement (CQI) became common in manufacturing industries, and part of the strategies of healthcare organizations across the world. Since the early 1990s healthcare reforms in developing countries have coincided with increased interest in achieving enhanced efficiencies and quality improvements in the healthcare delivery system, both in the public and private settings. Over the past three decades, there has been

a shift towards evaluation of process measures as well as results in the health sector in addition to inputs and sustainability of results has been linked with effective quality management processes. Similarly, during the recent past, there has been an emphasis towards quality improvement rather than focusing attention just on quality attainment.

Quality and safety have been recognized as key issues in establishing health systems that can deliver accessible, effective and responsive healthcare services. While the public at large holds the governments accountable for the quality of healthcare, there is growing evidence of suboptimal outcomes because patients are not provided appropriate treatments timely because of poorly organized health care services. There is evidence that quality methods can help to solve the challenges faced by low and high income countries alike. There is however, likelihood of wasting resources if the methods and approaches are not appropriate for the systems. Similarly, poor implementation strategies, inadequate use of data to assess working of actions and inconsistent efforts can also hamper producing desirable results. Under the World Health Organization's constitution, "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being". This suggests that the states are under obligations to adopt measures aimed at achieving universal access to healthcare without discrimination. There challenges to introducing modern approach to safety and quality in healthcare are more compared with other industries and the view that the patients and families are the key collaborators in ensuring safety and quality is strongly held.

There are many different views about the best way to improve quality of healthcare services with standardization being used by most of the healthcare systems across the globe through which standards as to how to provide effective and safe care are prescribed and enforced. The standards provided in the form of Guidelines, cover both, management activities as well as the activities performed to deliver healthcare services are used as a yardstick to monitor and measure the quality of healthcare. There is a corresponding inclination to use trainings as intervention facilitate personnel to follow standards and solve problems through job aids and supervision. The process is documented and where standards are not followed, supervisors and managers take corrective action. Patient safety is fundamental to delivering essential healthcare services that meet the benchmark of quality and there is a clear consensus across the world that quality health services should be effective, safe and people-centered. Further, to realize the benefits of quality, the provision of healthcare services must be timely, equitable, integrated and efficient.

1.2 Impact of Unsafe care on Healthcare Delivery Systems

Each year, millions of patients are reported to suffer injuries or die because of unsafe and poor-quality healthcare. Many risks associated with healthcare including the following are emerging as major challenges for patient safety and contribute significantly to the burden of harm due to unsafe care:

I. Medication errors, a leading cause of injury and avoidable harm in health care systems globally, with associated cost implications estimated at US$ 42 billion annually [1].

ii. Incidence of Health care-associated infections (HAIs) is 7 and 10 out of every 100 hospitalized patients in high-income and low- and middle-income countries respectively.

iii. Unsafe surgical procedures cause complications in up to 25% of patients and almost 7 million surgical patients suffer significant complications annually, out of which 1 million die during or immediately following surgery [2].

1- WHO: Patient Safety; 9th March 2019
2- WHO: Ten Fact on patient Safety, Sept 2019

iv. Unsafe injections practices in healthcare settings can transmit infections, including HIV and hepatitis B and C, and pose direct danger to patients and health care workers.

v. Diagnostic errors occur in about 5% of adults in outpatient care settings, more than half of which have the potential to cause severe harm whereas in most people the suffering due to diagnostic error is lifetime.

vi. Unsafe transfusion practices expose patients to the risk of adverse transfusion reactions and the transmission of infections and the data reports an average incidence of 8.7 serious reactions per 100 000 distributed blood components.

vii. Radiation errors involve overexposure to radiation and cases of wrong-patient and wrong-site identification with an estimated incidence being around 15 per 10 000 treatment courses.

viii. Sepsis is frequently not diagnosed early and since the infections are often resistant to antibiotics, they can rapidly lead to deteriorating clinical conditions, affecting an estimated 31 million people worldwide and causing over 5 million deaths per year.

ix. Deep Venous thromboembolism (DVP), one of the most common and preventable causes of patient harm, contribute to one third of the complications attributed to hospitalization and an estimated 3.9 million cases in high-income and 6 million cases in low- and middle-income countries suffer DVP annually.

1.3 Setting Service Delivery Standards for Promoting Safe Healthcare

Setting service delivery standards and indicators is an established practice for continuously improving the provision of quality services in the health sector. Joint Commission International (JCI) in the USA is one such organisation that sets standards to improve the quality of health services against such standards. Likewise, the Quality Care Commission in the UK ensures clinical governance with the help of a system of standard setting and facilitating compliance.

The 'Indian Public Health Standards' were introduced in 2005 and since then the Quality Council of India expanded their scope with the launching of 'Standards for the Health and Wellness Industry' in 2008. The Australian Council on Healthcare Standards was initiated in 1974 that has facilitated the development of the New Zealand and Singapore Councils. La Haute Autorite de Sante is the French equivalent. Accreditation Canada (formally the Canadian Council on Health Services Accreditation) became independent from the Joint Commission for Accreditation of Hospitals (JCAH) in 1953.

The Quality Holistic Accreditation (QHA) Trent Accreditation Scheme is based in the UK and Europe and has serviced hospitals in Asia. The Regional countries including Pakistan, India, Bangladesh, Kazakhstan, China and Iran have a number of hospitals that are Internationally.

1.4 Minimum Service Delivery Standards for Hospitals

Under its legal mandate, provided under the PHC Act 2010, the Punjab Healthcare Commission developed and enforced the Minimum Service Delivery Standards (MSDS) and associated Indicators for Hospitals. The primary objective of standardization was to introduce a culture of Clinical Governance grounded in the principles of responsibility and accountability to subsequently improve the quality, safety and efficiency of healthcare service delivery.

The standards, a product of extensive consultations with health experts having national and international standings and the relevant stakeholders, were endorsed by the Technical Advisory Committee (TAC) after though scrutiny, approved by the Board of Commissioners (BOC) of the PHC and notified by the Government of Punjab in 23rd October 2012. The MSDS comprises of a total of 30 Standards and 162 indicators is based on internationally acceptable framework covering all the functional areas of healthcare establishments; the clinical and management aspects, inter-alia, ranging from Care of Patients and Management of Medication to Continuous Quality Improvement, Infection Control and Information Management Systems. The MSDS has been adapted in the local context for ensuring that the standards are practically applicable and each indicator has a scoring matrix to assess compliance of Standards.

1.5 MSDS – Salient Features

The MSDS focus on institutionalizing quality assurance processes at the HCEs that reduce the risk of preventable harm to patients through standardizing healthcare service reducing variations in service delivery that may be detrimental to patient safety. While standards broadly pertain to clinical care as well as operational management, the prescribed procedures and practices are interdependent. When implemented together, the standards prevent the avoidable errors in the healthcare delivery; thus protecting the patients from harm as patient safety is the core theme and outcome of the standards.

Standards addressing the clinical care area prescribe cross-functional, overarching policies to avoid errors while conducting investigations or dispensing treatment. These include appropriate protocols for patient identification prior to any procedure, and systems to ensure that only qualified and trained personnel perform or supervise services such as laboratory or imaging tests, administration of anesthesia or medication, performance of surgical procedures, and provision of obstetrical care, etc.

At the same time, the MSDS also include specific policies prescribed for certain aspects of healthcare service delivery, where lapse may pose a direct and significant risk to patients. In cases where use of blood or blood products is involved, the MSDS direct proper screening of donors, safe administration of blood to recipients and to monitor and analyze real and suspected blood transfusion reactions and take corrective actions. The MSDS also require the management and clinical leadership at the HCEs to prescribe such policies for their internal functioning, and hence, are as such non prescriptive.

1.6 Sequential Review of the MSDS

Initially, the MSDS was applied to all hospitals in Punjab, including, the mega tertiary care hospitals in the major urban cities, the medium size healthcare establishments (HCEs) in the peripheral districts and the smaller peripheral hospitals providing varying scope of indoor services. Few months after the enforcement, it was revealed that separate set of standards need to be prescribed at smaller hospitals having less than 50 beds while

the current MSDS would be implemented at hospitals having more than 50 beds, falling under the category I HCEs. The PHC therefore, prescribed dedicated set of standards for the hospitals having less than 50 indoor beds, as category II HCEs that were notified by the Government of Punjab in 18th October 2014. This MSDS was however, further modified into four sets to match the scope of services of different level of HCEs, sub categorized into; category II A (31 to 49 beds), category II B (16 to 30 beds), category II C (up to 15 beds) and the Rural Health Centres (RHCs), with up to 20 beds and providing primary healthcare and basic surgical and diagnostic services. The realization that in the current format, some of the indicators in the MSDS for category I HCEs are prone to subjective assessment and scoring, the PHC embarked upon its revision. It was envisaged to make MSDS implementation and assessment friendly through addressing the element of subjectivity and while ensuring that the quality of care and patient safety is not compromised.

1.7 The Review Process

As part of revision process it was considered to seek feedback from the PHC field teams as well as from the focal persons of the respective category of HCEs; implementers of the MSDS. A google form was shared with the two categories of who were asked to furnish their views in terms of compliance of standards and associated indicators in ten functional areas of the MSDS currently in enforced in the Category I HCEs. Keeping in view the current status of compliance with the MSDS by the HCEs for acquiring PHC license, it was decided not to add new standards and indicators while restricting the revision to the extent of rephrasing only for the sake of facilitating the understanding. The MSDS has therefore, been edited and revised keeping in view the comments and feedback while ensuring that the number of standards and indicators as well as their essence is not changed.

1.8 Revised/ Edited version of the MSDS

1.8.1 Structural Revision

It has been observed that the current MSDS provides the Standards and associated indicators in each of the ten functional areas related to organizational management and the clinical care of patients. Description of each indicator is followed by the survey process and scoring methodology, and at times the chances of subjectivity in the assessment and scoring cannot be ruled out. It was therefore, considered worthwhile to enlist compliance requirements in respect of each indicator at the end of its description and before the scoring process to facilitate assessment and also minimize / eliminate the subjectivity in scoring. In addition, it was decided to supplement the scoring matrix by providing a checklist entailing structured compliance requirements for each indicator in order to facilitate the field teams.

1.8.2 Contextual Revision

In line with the feedback from the PHC Field Teams and the Focal Persons of the HCEs, some indicators have been rephrased so that the assessors as well as the implementers can clearly understand the requirements of the standards and indicators. The contextual revisions also included removing reference to the legislations that have become obsolete and add the newer ones.

The document in hand has accordingly, been modified by the PHC team of Clinical Governance and Organizational Standards as revised edition of MSDS for category I HCEs seeking professional inputs from the assessment teams as well as the implementers. It incorporates the intent statement that highlight the importance and requirement of each standard besides enlisting the compliance requirements and assessment

methodology for each indicator to make the scoring process more objective. Addition of the checklist with the scoring matrix entailing structured compliance requirements for each indicator will further facilitate the assessors and also eliminate the subjectivity in the scoring process.

PHC is pleased to notify the edited version of the MSDS comprising 30 "Foundation Standards" and 162 associated Indicators for implementation at the category I HCEs, in Punjab[3] , the Hospitals having more than 50 beds. The document incorporates the summary of each functional area, and compliance requirements enlisted after description of each indicator and also provides assessment methodology. Description of the text in some of the indicators has been slight rephrased and while references of obsolete legislation have been replaced with the newer ones.

3- In the 3rd reprint only minor printing errors were rectified while in the current 4th reprint provide checklist including compliance requirements for each indicator.

02

Standards

2 - Standards

2.1 Functional Area Outline: 1

Access, Assessment and Continuity of Care (AAC)

Standards: 2 (1 - 2)
Indicators: 14 (1-14) (9 + 5)

Standard 1

Laboratory Services

- Scope of Lab services
- Availability of qualified and trained personnel
- Documented policies and Procedures for guidance of Lab processes
- Availability of Lab results in the defined time frame
- Immediately reporting of critical results
- Outsourcing of test not available on site

Standard 2

Laboratory Services

- Legal and Regulatory Requirements of imaging services
- Scope of imaging services
- Training and qualification of radiology staff
- Policies and Procedures for identification and safe transportation of patients
- Reporting Imaging Results in a defined Time frame
- Immediate Intimation of Critical Results
- Quality Assurance Activities
- Outsourcing imaging test not available in house

Core elements of the Functional Area:

1. Laboratory Services meet the clinical requirements of Patients
2. Imaging services as per clinical requirements of Patients
3. Legal requirements for radiology services
4. Qualified and Trained Staff

2.1 Access, Assessment, and Continuity of Care (AAC)

2.1.1 Standard 1. AAC-1:

Laboratory services are provided as per the requirements of patients

Intent Statement

This standard requires the HCEs to provide the onsite/offsite laboratory services to meet the clinical requirements of patients and as prescribed by the clinicians/treating doctors in the hospital to support establishing the diagnosis and review of the progress. This requires that the laboratory services of the HCE, onsite or / and offsite should match the diagnostic requirements of clinical services provided by various specialties/ the departments of the HCE.

The standard also requires that adequately qualified and trained personnel perform and/or supervise the investigations. Further, there should be documented policies and procedures to guide proper identification, safe transportation, proper handling, processing and disposal of specimens. The standard further require that the results of tests are made available within the defined time frame, whereas critical results and notifiable diseases are reported immediately to the concerned personnel/authorities. Further, the laboratory tests not available in the onsite laboratory in the HCE are outsourced to organization(s)/ labs based on their quality assurance system and independent accreditation.

Ind. 1 Scope of the laboratory services is commensurate to the clinical services provided by the organization.

Survey Process

This will require the surveyors to clearly understand the full scope of services provided at the particular healthcare establishment and observation of the diagnostic facilities provided both, on site and off site. Check regarding the test/services outsourced to the external organization/s/ laboratory and validate arrangements through review of the MOU[4]. The in house as well as outsourced lab should be easily accessible to the patients and staff with the help of direction boards/signage.

Compliance Requirements

i. The in house hospital lab is easily accessible to the patients and staff with the help of direction boards/ signage
ii. List /declared scope of clinical services
iii. List of Lab tests needed to meet the requirements as developed in consultation with the available clinical staff
iv. List of Lab tests available onsite
v. Facilities for the test including but not limited to the following basic Hematology and Biochemistry tests should be available on 24/7 basis even in case all the Lab Services are outsourced:
    a. Routine Blood Examination / CBC
    b ESR
    c. Blood Sugar

4- Patients should be informed about laboratory tests that are outsourced.

d. BT and CT
e. Blood Grouping
f. Screening for Hepatitis B & C (Rapid Tests subject to the regulatory approvals)
g. Urine RE
h. Pregnancy Test (Rapid strip based) etc.

vi. Tests not available in house are outsourced on the basis of an MOU

Assessment

	Compliance Requirement	Evidence	
i.	Lab accessible with the help of signage	Observation	Interview
ii.	List /declared scope of clinical services	Document Review	
iii.	List of onsite available Lab tests*	Document Review	
iv.	Basic Hematology and Biochemistry tests available on 24/7 basis	Observation	Interview
v.	Routine specialty specific tests listed by the concerned clinicians /HODs	Document Review	

Scoring

- If laboratory services at the healthcare establishments and any qualified outsourced services support the scope of services, then score as **fully met.**
- If there is an insufficient scope of laboratory diagnostic procedures (both in house as well as outsourced), to support the services provided by the hospital, then score as **not met.**

Ind. 2 Adequately qualified and trained personnel perform and/or supervise the investigations.

Survey Process

Each laboratory personnel including the technicians/ technologists, section heads and laboratory head/ pathologist should have the qualification/s prescribed for the laboratory staff equivalent to the job criteria. Review a sample of 3 human resource files or files of 25% laboratory staff, whichever is greater. This will include the files of laboratory technical and supervisory staff/in charge/HOD to determine if their qualifications, experience and training match the job requirements, including operating the equipment being used, supervising analysis/ processing and reporting the results. A documented CME Programme should also be in place and implemented for Continuous Professional Development[5] of the staff. There should be a documented duty roster for all the technical staff with the defined mechanism to ensure their availability accordingly.

The Job Descriptions and Performance Evaluation Criteria for Medical, Nursing and Paramedical Staff developed under the Punjab Devolved Social Services Programme, Government of the Punjab, 2008-09 that inter-alia, defines the required level of qualifications, training and experience for the laboratory staff can be consulted for guidance.

5- A CME programme administered by a recognized professional college/institution.

Compliance Requirements

i. Pathologist /laboratory head and section head/s holding qualification/s registered with PM&DC/PMC for overall supervision
ii. Technicians having Qualification registered with PMF/ technologists having recognized qualification for technical and support services
iii. List of laboratory staff with duty roster for service provision on 24/7 basis
iv. Evidence of availability of qualified staff according to the defined job criteria and duty roster
v. Evidence of supervision and issuance of reports by the Pathologist and availability of qualified section head/s in case of labs providing special range of laboratory tests like haematology, histopathology, microbiology etc.

Assessment

	Compliance Requirement	Evidence
I.	Qualified Pathologist having qualification/s registered with PM&DC/ PMC	Document Review
ii.	Qualified Technicians/ technologists	Document Review
iii.	List of laboratory staff with duty roster for service provision on 24/7 basis with a mechanism to ensure presence	Document Review
iv.	Availability of qualified staff according to the defined job criteria and duty roster	Document Review
v.	Evidence of supervision and issuance of reports by Pathologist	Document Review

Scoring

- If the sample individuals' qualification/s match the requirements of the job criteria, or if there are only minor variances (such as only 4 years of experience instead of 5), the duty roster is available and there is mechanism to ensure their presence then, score as **fully met.**
- If the duty roster and a mechanism to ensure their presence is available but only one technician does not have the qualification required by the job criteria, then score as **partially met,** provided that there is evidence of enhanced supervision or training of this individual.
- If two or more technicians do not have the required qualifications prescribed as per the job criteria, then score as **not met.**

Ind. 3 Policies and procedures guide the : 1. Specimens Collection, 2. Identification, 3. Handling, 4. Safe transportation, 5. Processing and 6. Disposal of specimens

Survey Process

Review the laboratory policy and procedures to validate that it covers ALL the 6 compliance requirements. Then, by observation check for example, how the patients are positively identified for taking the blood and other samples, how the specimen is labelled and further handled. It is always important to verify that the policy or procedure is not just written, but is actually implemented and followed. Ask operational staff about the requirements to establish if they are aware of the policies and procedures and have received appropriate orientation and training.

Compliance Requirements

i. Documented policies and procedures / SOPs regarding the following activities in the laboratory:
   a. Sample Collection/ phlebotomy
   b. Identification of patients and samples
   c. Sample handling
   d. Safe transportation of samples
   e. Processing/ analysis of samples
   f. Disposal of specimens

ii. Documented evidence of orientation and training of staff on Lab Policies & procedures

iii. Awareness of staff about the policies and procedures

Assessment

	Compliance Requirement	Evidence	
I.	Documented policies and procedures/SOPs	Observation	Document Review
ii.	Evidence of orientation and training of staff on Lab Policies & procedures	Interview	Document Review
iii.	Awareness of staff about the policies and procedures	Interview	Observation

Scoring

- If there are policies and procedures for ALL the 6 requirements, and evidence that the manual clearly defining the procedures is present at the work place, that documented training has been delivered and that the policies and procedures are followed, then score as **fully met.**
- Since this is significant for **patient safety** (misidentified patient and mislabeled specimens are a common source of laboratory errors), if there are no documented policies and procedures for ALL 6 requirements or if the same are not implemented, then score as **not met.**

Ind. 4 Laboratory results are available within a defined time frame

Survey Process

While visiting the laboratory, review the document defining the time frames for the test results to be available. Then, see if the laboratory has data to show that the time lines are being met. Surveyors may further validate timely reporting, while in an inpatient unit, by reviewing 3-5 medical records. Look for the time of receipt of sample in the lab and compare with the time when the result was available. Evidence should provide 95% compliance in routine and 100% in emergency test reports.

Compliance Requirements

i. Documented turnaround time frames for Routine and Emergency tests documented

ii. Evidence of 95% compliance in routine and 100% in emergency test reports available in:

a. Lab record for receipt of samples and reporting of test results.

b. In-patient files for timing of physician orders, sending/taking the samples to lab and receipt of test reports.

Assessment

	Compliance Requirements	Evidence	
i.	Documented turnaround time frames for Routine and Emergency	Document Review	
ii.	a. Lab record for receipt and reporting of sample b. In-patient files for timing of physician orders, sending/taking the sample to lab and receipt of test reports	Interview	Document Review

Scoring

- If the defined time lines for reporting results are met without any delays in all cases (both emergency and routine tests) or with occasional delays in only up to 5 percent in cases of routine tests only, then score as **fully met.**
- If the defined time lines for results are met without any delays in cases of emergency tests but there are delays ranging from 5 to 10 percent in cases of routine tests, then score as **partially met.**
- If the defined time lines for results are not met in any case of emergency tests or there are delays higher than 10 percent in cases of routine tests, then score as **not met.**

Ind. 5 Critical results are reported immediately to the concerned personnel

Survey Process

The laboratory should have defined critical values for ALL relevant tests and should have documentation (such as a log book) that the critical results and priority diseases are immediately reported on detection, to relevant persons/authorities as applicable. This is a significant patient safety issue.

Compliance Requirements

i. List of defined critical values of the tests results including priority diseases

ii. Protocols for immediate reporting of critical values of the test result including detection and reporting of priority to relevant persons/authorities as applicable

iii. Evidence that critical values of the test result/detection of priority diseases are reported to the relevant persons/authorities and include:

   a. Name of patient
   b. MR Number input required
   c. Test result/s
   d. Date and time of reporting
   e. Date and time of informing
   f. Identification of informing person
   g. Identification of means of communication (verbal, written or electronic)
   h. Person/s to whom informed (The patient/responsible ward staff/requesting doctor)

Assessment

	Compliance Requirements	Evidence
i.	List of defined critical values of the tests results as well as priority diseases	Document Review

ii.	Person/s to whom reported	Document Review
iii.	Evidence that critical values of the test result/detection of priority diseases are reported	Document Review

Scoring

- If there are defined critical values, SOPs for reporting and documentation that they are reported as soon as available, then score as **fully met.**
- If the critical values are not defined or if there are no SOPs or no evidence that they are reported as soon as available, then score as **not met.**

Ind. 6 Laboratory tests not available in the organization are outsourced to organization(s) based on their quality assurance system and independent accreditation

Survey Process

Look for the documentation of the laboratory test not available onsite and outsourced to some other organization(s) /laboratories. Determine which laboratory or laboratories the hospital uses for outsourced services and look for the documentation/ MOU in this regard. Also look for the documentation to ascertain that the laboratory or laboratories have demonstrated quality, for example registration/ licensing by the PHC, accreditation with the Pakistan National Accreditation Council (PNAC) or any other such authority as an evidence of quality assurance and is easily accessible to the clients. If the hospital has used a referral laboratory for some time and is comfortable that the results are accurate and timely, this experience can be sufficient to demonstrate that it meets the quality requirement. The arrangements including quality Indicators and turnaround times should be specified in a formal contractual arrangement.

Compliance Requirements

I. Outsourced tests listed for the information pf patients, staff and surveyors
ii. Documented MOU signed with the outsourced Laboratory, clearly stating details of responsibilities of either party including turnaround time.
iii. Evidence of QA System followed by the contracted organization/ laboratory to the satisfaction of the HCE and registered/licensed with PHC

Assessment

	Compliance Requirements	Evidence
i.	Outsourced tests listed for the information pf patients, staff and surveyors	Document Review
ii.	Documented MOU signed with the outsourced Laboratory including turnaround time	Document Review
iii.	Evidence of QA system followed by the contracted organization/ laboratory registered/licensed with PHC	Document Review

Scoring

- If there is documented evidence that the referral laboratory or laboratories deliver quality results as defined in the MOU (even if only by the hospitals experience in the first year), then score as **fully met.**
- If there is no or limited evidence that the referral laboratory demonstrates quality, then score as **not met.**

Standard 2. AAC-2:

Imaging services are provided as per the clinical requirements of the patients

Intent Statement

This standard requires the HCEs to provide the onsite/offsite radiology/imaging services as per the clinical requirements of patients as prescribed by the clinicians/treating doctors in the hospital. This implies that the scope of radiology diagnostic services of the HCE should match the type and range of services being provided by the available clinicians from various departments of the HCE. The standard also requires that personnel performing and/or supervising the imaging services hold the prescribed qualification/s and are accordingly trained. The documented policies and procedures should also guide the safety of patients and the care providers. The time frame for reporting the results should be defined and there should be documented procedures to ensure that reports are available within the time frame, whereas the critical results are reported immediately to the concerned personnel/authorities. The diagnostic services not available in the HCE are to be outsourced to organization(s) based on their quality assurance system and independent accreditation, like registration / licensing with the PHC. The policies to ensure radiation protection as well as quality assurance should be documented and implemented in the radiation department.

Ind. 7 Imaging services comply with legal and other requirements

Survey Process

There should be documentary and physical display of compliance with ALL legal and regulatory requirements in the Radiology Department. The key staff should be aware of the regulatory requirements and comply the same accordingly.

Compliance Requirements

i. Valid PNRA certificate in respect of compliance with the radiation protection requirements
ii. Awareness of the staff regarding radiation protection requirements
iii. Demonstrable evidence of compliance of radiation protection requirements

Assessment

	Compliance Requirements	Evidence	
i.	Valid PNRA certificate regarding radiation protection requirements	Document Review	
ii.	Arrangements for complying the radiation safety measures	Interview	Document Review
iii.	Demonstrable evidence of compliance	Document Review	

Scoring

- If supporting documents are present in the department and staff is aware of the content and clearly applying the requirements, then score as **fully met.**
- If the legal and regulatory requirements are present and understood but not fully applied, then score as **partially met.**
- If there are no regulatory requirements present and most staff members are unaware of their compliance obligations, then score as **not met.**

Ind. 8 Scope of the imaging services meets the requirement of the clinical services provided by the organization

Survey Process

This indicator requires an understanding of the full scope of services provided at the hospital and observation of the diagnostic facilities provided both, onsite and offsite which should be easily accessible with the help of direction boards/ signage. A full complement of imaging services should also be provided to cater for emergency situations that may arise from the services delivered by the hospital. The HCEs providing invasive imaging services must have adequate back up and support service in the event of an emergency. This involves resuscitation, and in some cases, emergency surgery when cardiac procedures are involved.

Compliance Requirements

i. List capturing the scope of clinical services provided in the HCE
ii. List of imaging services available onsite and easily accessible with the help of direction boards/ signage
(X-Ray, CT scan, MRI, Fluoroscopy, Ultrasound etc.)
iii. List of imaging services that are not available to meet the requirement of clinical services
iv. Displaying the list of outsourced imaging services to match the requirements at number iii
v. MOU with the outsourced imaging service
vi. Certification of the PNRA and PHC registration/ license as applicable in respect of the in house as well as outsourced imaging service
vii. Availability of complement of imaging services to cater for emergency situations that may arise from the services delivered by the hospital (portable etc.)
viii. Adequate arrangements for handling an emergency event including resuscitation and emergency surgery in some cases

Assessment

	Compliance Requirements	Evidence	
i.	List of clinical services provided in the HCE	Document Review	
ii.	List of available imaging services and easily accessible with the help of direction boards/ signage (e.g. X-Ray, CT scan, MRI, Fluoroscopy, Ultrasound etc.)	Document Review	Observation
iii.	List of imaging services not available on site /outsourced	Document Review	
iv.	MOU with the outsourced imaging service	Document Review	
v.	Compliance of regulatory requirements - Certification of the PNRA and PHC etc. in respect of in house and outsourced imaging service	Document Review	
vi.	Complement of imaging services to cater for emergency situations	Document Review	
vii	Adequate back up and support service in the event of an emergency	Document Review	Observation

Scoring

- If the above listed requirements at I to viii are complied, then score as **fully met.**
- If any of the above requirements are not complied then, score as **not met.**

Ind. 9 Adequately qualified and trained personnel perform supervise and interpret the investigations

Survey Process

Each member of the Radiology Department should have a job criteria that defines the required level of qualification, training and experience for the staff of imaging and radiology diagnostic services. The surveyors should review the human resource files of 3-5 or 25% staff (whichever is greater) of the department including radiographers /technicians/ technologists and supervisors/ in charge radiologist to determine if their qualifications, training and experience match the requirements of the job. This would include job/s related to operating the equipment that is being used and to performing supervisory functions and reporting the results. Documented Continuous Medical Education Programme[6] should be in place and implemented for Continuous professional development of the staff. The Job Descriptions and Performance Evaluation Criteria for Medical, Nursing and Paramedical Staff, developed under the Punjab Devolved Social Services Programme, Government of the Punjab, 2008-09 inter-alia prescribes the job specifications and equivalent qualification/s for the radiology staff and can be used by the implementers for guidance.

Compliance Requirements

I. Qualified Radiologist having Post-graduation in Radiology registered with the PMDC/PMC as the overall supervisor/HOD
ii. List of qualified radiographers/radiology technicians with qualification registered with the PMF/ / technologist with recognized qualification
iii. 24/7 Duty roster for the imaging technicians/ radiographers / technologist
iv. Radiological reporting only by the qualified and registered Radiologist provided that tele-reporting of radiological images by the Radiologist under standardized IT based arrangement/PACS without compromising patient safety and care is permissible
v. Presence of MO/PG trainee in cases where IV contrast is administered and exposure by qualified Technicians /radiographers/technologist/is ensured during the absence of Radiologist
vi. Staff is available as per the duty roster.

Assessment

	Compliance Requirements	Evidence	
i.	Qualified Radiologist having Post-graduation in Radiology registered with the PMDC/PMC as the overall supervisor/HOD	Document Review	
ii.	List of qualified radiographers /radiology technicians/ technologist/s	Document Review	
iii.	24/7 Duty roster for the radiographers /imaging technicians	Interview	Document Review
iv.	Radiological reporting only by the qualified Radiologist	Document Review	

6- A recognized program administered by a professional college/council or equivalent

v.	Presence of MO/PG trainee and exposure by qualified radiographers / Technicians	Interview	Document Review
vi.	Staff is available as per the duty roster.	Observation	

Scoring

- If qualification/s of the sampled individuals including radiologist/s and radiographers /radiology technicians match the requirements in the job criteria, or if there are only minor variances (such as only 4 years of experience instead of 5), then score **fully met.**
- If the radiology department is supervised by qualified Radiologist but only one technician does not have the qualifications required by the job criteria, then score as **partially met**, provided that there is evidence of enhanced supervision or training of this individual.
- If the radiology department is not supervised by qualified Radiologist or if two or more technicians do not have the required qualifications as per the JDs, then score as **not met.**

Ind. 10 Policies and procedures guide identification and safe transportation of patients to imaging services

Survey Process

Review the policies and procedures and specifically look for how the patient is positively identified and how it is ensured that the correct imaging procedure is done on the correct patient. Look for evidence that specific medical attendance or equipment is available and provided if needed to accompany the patient to the department and that there is a clear process to ensure that this is practiced. Specifically look for evidence (by observation and interview of staff) that the patient is positively identified.

Compliance Requirements

i. SOPs and requirement for safe transportation
ii. SOPs for safe Identification of patient
iii. SOPs to identify and exposure for imaging correct site, side and area
iv. Evidence of training the staff on imaging Policies and procedures/SOPs
v. Awareness of staff about the policies and procedures /SOPs

Assessment

	Compliance Requirements	Evidence	
i.	SOPs and requirement for safe transportation of patient	Interview	Document Review
ii.	SOPs for safe Identification of patient	Interview	Document Review
iii.	SOPs to identify and exposure for imaging correct site, side and area	Interview	Document Review
iv.	Evidence of training the staff on imaging Policies and procedures/SOPs	Document Review	
v.	Awareness of staff about the policies and procedures /SOPs	Interview	Document Review

Scoring

- If there are documented policies and procedures/SOPs for patient`s identification and safe transport and the same are implemented, then score as **fully met.**
- If either there are no policies/SOPs or that there is no evidence that they have been implemented and are being followed, then score as **not met.**

Ind. 11 Imaging results are available within a defined time frame

Survey Process

During visit to the Radiology Department, the surveyor should review the document/s defining the time frames for availability of the imaging services and issuance of reports. Then, see if the department has data to show that the times are being met. For further validation of compliance to the defined time frame, the surveyors need to review 3-5 medical records while visiting an inpatient unit. Look for the time the imaging test was conducted, and compare with when the report was available. Evidence should provide 95% compliance in routine and 100% in imaging and reporting of emergency cases.

Compliance Requirements

i. Turnaround time frames for routine and emergency imaging and reporting defined, and documented
ii. Evidence of 95% compliance in routine and 100% in reporting of emergency tests:
    a. The record of Radiology Department regarding arrival of the patient, imaging and reporting
    b. In-patient files for the timing of physician orders, sending the patient for imagining and receipt of reports

Assessment

	Compliance Requirements	Evidence
i.	Defined / documented turnaround time frames for routine and emergency imaging and reporting	Document Review
ii	Evidence in the record (Radiology Department and In-patient files) of compliance of reporting of tests	Document Review

Scoring

- **I**f the time frame for reports to be available are defined and met without any delays in all cases (both emergency & routine tests) or with occasional delays which are not more than 5 percent in cases of routine imaging reports only, then score as **fully met.**
- If the time frame for reports to be available are defined and are met without any delays in cases of emergency imaging and reporting but there are delays ranging from 5 to 10 percent in cases of routine imaging and reporting, then score as **partially met.**
- If the defined time frame for reports in any case of emergency are not met or if there are more than 10% delays in cases of routine imaging/reporting, then score as **not met.**

Ind. 12 Critical imaging results are intimated immediately to the concerned personnel

Survey Process

Unlike the laboratory, critical findings on images depend to a great extent on the clinical judgment of the radiologist. However, the department should at least have some general guidelines and a way to document that the critical findings are reported as soon as possible. This is a significant patient safety issue.

Compliance Requirements

i. List of defined possible critical findings of the tests results
ii. Identification of means of communication (verbal, written or electronic)
iii. SOPs for immediate reporting of critical findings of the imaging result/s that should include:
   a. Name of patient
   b. MR number of patient
   c. Imaging result
   d. Date and time reporting
   e. Date and time of informing
   f. Identification of reporting and the concerned person/physician to whom communicated

Assessment

	Compliance Requirements	Evidence	
i.	List of defined possible critical findings of the tests results	Document Review	
ii.	SOPs for immediate reporting of critical findings of imaging result/s	Document Review	
iii.	Identification of means of communication (verbal, written or electronic)	Document Review	Interview
iv.	Evidence that the critical findings of the tests results are reported immediately to the concerned person/s	Document Review	

Scoring

- If there are guidelines to manage critical findings and there is documentation that they are reported as soon as available, then score as **fully met.**
- If there is no understanding of what constitutes a critical imaging finding, or if there is no defined process to report them as soon as available or if these are not consistently implemented, then score as **not met.**

Ind. 13 Quality Assurance activities are evident in the Imaging Department

Survey Process

There should be documented evidence that a Quality Assurance (QA) plan is active in the radiology/ imaging department. This should include observation of activities such as a register of repeat images due to image quality related reasons, training of staff maintenance of equipment and recording and reporting of any adverse occurrences.

Compliance Requirements

i. A copy of the QA plan, covering the following along with the evidence that at least 80% of staff is aware of *its contents and the associated activities:*

a. Standardized request form used for imaging requisition across the HCE
b. Periodic inspections, calibration and preventive maintenance of the equipment as per OEM guidelines
c. Display of safety warning signs on the doors
d. Training of the staff on radiation protection and monitoring for radiation exposure on quarterly basis
e. Provision and use of radiation protection apron and thyroid and gonads shields etc.
f. SOPs regarding due care for radiation exposure of pregnant woman and evidence that these are practiced
g. SOPs that MO/WMO accompanies the patient/s for special / interventional procedures
h. Emergency trolley / resuscitation facilities available in the radiology department
i. Disposal of radioactive waste according to the Waste Management Rules 2014
j. Complete and updated record of repeat investigations

Assessment

	Compliance Requirements	Evidence	
i.	A copy of the QA plan, covering all the compliance requirements	Document Review	
ii.	Evidence that at least 80% of staff is aware of its contents and the associated activities	Document Review	Interview

Scoring

- If a copy of the QA plan is available along with evidence that at least 80% of staff is aware of its contents and the documented associated activities, like repeat exposures, maintenance of equipment, and training of staff etc. then score as **fully met.**
- If there is no copy of the QA plan or if less than 80% of staff are aware of its contents, then score as **not met.**

Ind. 14 Imaging tests not available in the hospital are outsourced to organization(s) based on their quality assurance system and compliance with applicable laws and regulations

Survey Process

There should be documented evidence that the radiology services to which patients are referred in case the same are not available on site, are licensed by the Pakistan Nuclear Regulatory Authority (PNRA), registered / licensed with the PHC and that the hospital has a history of receiving timely and accurate reports from the referral radiology service commensurate with the clinical needs of the patient.

Compliance Requirements

i. Documented MOU with the outsourced diagnostic centre
ii. Outsourced tests are listed for the information of the clinicians / patients
iii. Evidence that the outsourced diagnostic centre meets the legal requirements i.e. licensed by the PNRA and registered / licensed by the PHC

Assessment

	Compliance Requirements	Evidence
i.	Documented MOU with the outsourced diagnostic centre	Document Review
ii.	Displayed list of outsourced tests for the information of patients	Document Review
iii.	Outsourced diagnostic centre is licensed by the PNRA and registered / licensed by the PHC	Document Review
iv.	Evidence that the outsourced diagnostic centre is delivering timely and accurate reports	Document Review

Scoring

- If the referral imaging services are approved by the PNRA, registered / licensed with the PHC and the hospital demonstrates sufficient experience to know that reports are timely and accurate, then score as **fully met.**
- If the referral imaging services are not approved by the PNRA or if the centre is not registered / licensed with the PHC or if there are significant problems with the quality of referral radiology services in terms of timeliness and accuracy then, scored as **not met.**

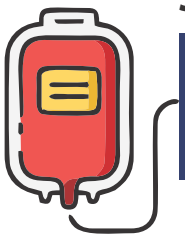
Functional Area: Care of Patients (COP)

Outline:
Standards: 5 (3- 7)
Indicators: 36 (15-50) (**22** + **14**)

Standard 3

Emergency Services

- Policies and Procedures for Emergency Care
- Policies for handling medico legal cases
- Patient receive care in consonance with policies
- Policy and SOPs provide guidance on Triage
- Staff awareness on emergency care
- Documentation regarding Patient transfer /referral



Standard 4

Rational usage of blood and blood products

- Docuemnted Policies & Procedures
- Safe Transfusion Services
- Informed Consent
- Training of Staff members
- Analysis of Transfusion Reactions

Standard 5

High Risk Obstetrical Patients.

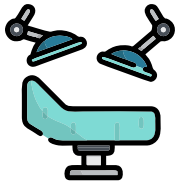
- Scope regarding care of High Risk Obstetric Cases
- Qualified & Competent staff
- Assessment of Maternal Nutritional status
- Arrangements for resuscitation of the Neonates
- Guaranteed Patient identification

Standard 6

Guidance on Administration of Anaesthesia

- SOPs for Administration of Anaesthesia
- Pre- Anaesthetic assessment by qualified staff
- Documented Anaesthetic Plan for each patient
- Immediate Pre-operative Re-evaluation
- Informed Consent taken by a qualified member of Anaesthetic team
- During Anaesthetic Monitoring
- Guaranteed identification of the patient for Anaesthesia
- Monitoring and Documentation of Post Anaesthetic Status
- Defined Criteria for the transfer of Patient
- Monitoring and Record of adverse Anaesthetic Events

Standard 7



COP undergoing Surgical Procedures

- Documented Surgery Related Policies and Procedures
- Documented Pre-Operative Assessment and Provisional Diagnosis
- Informed Consent by Surgical Team
- Documentation to Prevent Adverse Events
- Surgical procedures perform only by qualified persons Permitted by Law

Documented operative notes prior to transferring the patient

Documented Post-Operative Care Plan

Quality Assurance Programme

Surveillance of Operation Theatre Environment

Monitoring of Surgical Site Infection Rates

Core elements of the Functional Area:

1. Policies and Procedures for Emergency Care
2. Policies and Procedures for Rational Use of Blood and Blood Products
3. Policies and Procedures for Care of High Risk Obstetric cases
4. Policies and Procedures regarding Administration of Anaesthesia
5. Policies and Procedures regarding Surgical Procedures

Standard 3. COP-1:

Emergency services are guided by policies, procedures and applicable laws and regulations

Intent Statement

This standard requires the HCEs to have its Emergency services guided by policies, procedures and applicable laws so that service provision remains compliant to the regulatory statutory norms. To achieve this, the standard requires documented policies and procedures for emergency care that should also contain SOPs for handling medico legal cases, training of the staff to be conversant with the SOPs and provision of care to patients in consonance with the policies. It also requires SOPs regarding the triage of patients for initiation of appropriate care. Staff members are to be trained and made familiar with the policies and procedures for care of emergency patients. The standard also requires that admission or discharge to home or transfer to another organization are properly documented.

Ind. 15 Policies and procedures for emergency care are documented

Survey Process

Review the documented policies and procedures, which should cover the functioning and administration of the emergency area covering access through hassle free entrance and signage, triage, waiting times, registration/admission, legal reporting requirements, discharge and patient transfer etc.).

Compliance Requirements

I. Documented policies and procedures/SOPs covering the following aspects of functioning and administration of the emergency area:
   a. Un hindered Facility Entrance providing easy access supported by signage
   b. Reception
   c. Registration and guidance

ii. Checklist categorizing medical emergencies into:
   a. Non Medico-legal Emergencies
   b. Medico-legal emergencies

iii. SOPs regarding waiting time for:
   a. Patient waiting for assessment
   b. Patient under observation
   c. Patient waiting for admission
   d. Patient waiting for admission with no bed available
   e. Patient waiting for referral to another hospital
   f. Transfer/ shifting of patients within same HCE or another organization

iv. SOPs for
   a. Consent
   b. Clinical Laboratory and Radiology Services
   c. Operating/Procedure room, if required
   d. ICU/CCU care
   e. Patient Discharge
   f. Patients record
   g. Continuous Training of ER Staff

v. Triage SOPs

a. Defined triage process
b. Based on written algorithm
c. Based on actual clinical evaluations
d. Training and awareness of the staff

vi. Medico legal reporting
a. Listed types of medico legal cases (both brought by police and potential cases)
b. Contact list of local police station and referring HCE for conduct of the MLC and MLR.
c. Availability of statutory provisions for MLC and MLR.
d. Awareness regarding the above legal requirements

Assessment

	Compliance Requirements	Evidence		
i.	Documented policies and procedures / SOPs covering the following aspects of functioning and administration of the emergency area: a. Un hindered Facility Entrance providing easy access supported by signage b. Reception c. Registration and guidance	Observation		
ii.	Checklist categorizing medical emergencies into: a. Non Medico-legal Emergencies b. Medico-legal emergencies	Observation		
iii.	SOPs regarding waiting time for: a. Patient waiting for assessment b. Patient under observation c. Patient waiting for admission d. Patient waiting for admission with no bed available e. Patient waiting for referral to another hospital f. Transfer/ shifting of patients within same HCE	Interview	Document Review	
iv.	SOPs for a. Consent b. Clinical Laboratory and Radiology Services c. Operating/Procedure room, if required d. ICU/CCU care e. Patient Discharge f. Patients record g. Continuous Training of ER Staff	Observation	Interview	Document Review
v.	Triage SOPs a. Defined triage process b. Based on written algorithm c. Based on actual clinical evaluations d. Training and awareness of the staff	Observation	Document Review	

vi.	Medico legal reporting a. Listed types of medico legal cases (both brought by police and potential cases) b. Contact list of local police station and referring HCE for conduct of the MLC and MLR. c. Availability of statutory provisions for MLC and MLR. d. Awareness regarding the above legal requirements	Observation	Interview	Document Review

Scoring

- If there are documented policies and procedures covering all the above requirements, and the staff members are aware of policies and procedures, then score as **fully met.**
- If there are policies and procedures as above and only 1-2 staff members are not aware of those, or if only 1-2 requirements do not have documented policies and procedures, then score as **partially met.**
- If there are no policies and procedures, then score as **not met.**

Ind. 16 Policies and procedures for emergency care contain SOPs for handling medico legal cases and staff is conversant with the SOPs

Survey Process

The policy should define what types of cases should be reported and to whom (which agency) they should be reported to. The surveyor should review the record of reported cases and assess how they have been managed in terms of analysis and consequential changes, if required.

Compliance Requirements

i. Defining the "medico-legal" cases
ii. SOPs for handling medico legal cases
iii. Orientation of the Staff on SOPs
iv. Evidence that the SOPs are implemented

Assessment

	Compliance Requirements	Evidence	
I.	Defining "medico-legal" cases	Document Review	
ii.	SOPs for handling medico legal cases	Document Review	
iii.	Orientation of the Staff on the SOPs	Interview	Document Review
iv.	Evidence that the SOPs are implemented	Document Review	

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 17 The patients receive care in consonance with the policies

Survey Process

It need to be made sure that the staff is conversant with the policies for emergency care and the patients receive care in consonance with the policies. This will be surveyed by observation and interview with staff members. The policies should be readily available and understood by staff and embrace ALL the aspects of care being received by patients. There should be evidence of a process whereby the staff receive training to make them aware regarding the policies and associated procedures.

Compliance Requirements

i. Emergency care provision in accordance with SOPs
ii. Documented evidence of implementation of policies
iii. Names of the staff on duty including the consultants (onsite or on call) is displayed on the roster
iv. Round the clock coverage of specialized care is evident

Assessment

	Compliance Requirements	Evidence	
i.	Emergency care provision in accordance with SOPs	Document Review	
ii.	Evidence of implementation of policies	Document Review	
iii.	Names of the staff on duty including the consultants (onsite or on call) is displayed on the roster	Observation	Document Review
iv.	Round the clock coverage of specialized care is evident	Observation	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 18 Policies and procedures guide the triage of patients for initiation of appropriate care

Survey Process

Emergency policy contains SOPs regarding the triage of patients for prioritization and initiation of appropriate care. Look for a formal triage process, ideally based on a written algorithm. The most important issue is to validate that triage is based on an evaluation of the patient's presenting complaint and/or condition (clinical need) and NOT on time of arrival (first come, first served) or mode of arrival (ambulance versus walk-in). A walk-in patient may well have more emergent needs than the patient who arrived by ambulance. Existing standards on emergency management and disaster response should be followed.[7]

Compliance Requirements

I. Written Triage SOPs

7- In keeping with the National Disaster Management Agency and Government of Punjab hospital requirements for the management of disasters. – The Society of Emergency Physicians Pakistan (SEPP)

ii. Staff orientation on Triage SOPs
iii. Evidence that the Triage SOPs and processes are implemented based on actual clinical evaluation[8]

Assessment

	Compliance Requirements	Evidence	
I.	Written Triage SOPs	Document Review	
ii.	Staff orientation on Triage SOPs	Interview	Document Review
iii.	Practice and documentary evidence of implementation of triage process	Observation	Document Review

Scoring

- If there is triage process and SOPs, Triage is based on actual clinical evaluation and is carried out by appropriately trained staff using appropriate facilities, staff members are aware of SOPs and are applying the process based on actual clinical evaluation then, score as **fully met.**
- If there is a triage process, but it is not consistently based on at least a brief clinical evaluation of the patient using appropriate facilities, then score as **partially met.** Surveyor judgment is required since some presenting complaints (chest pain and acute respiratory distress) should trigger immediate attention even without a brief clinical evaluation.
- If there is no triage process or if it is on first come, first served basis, then score as **not met.**

Ind. 19 Staff members are familiar with the policies and trained on the procedures for care of emergency patients

Survey Process

The emergency department should be manned round the clock by staff EMOs/ CMOs and others duly trained in handling emergency cases and sufficient in number to cater for the work load. The Emergency should also have round the clock coverage of specialized care preferably on site. This is surveyed by observation and interview with staff members. Training and orientation should be documented in terms of contents and participation. There should be evidence that the staff are aware of the policies and procedures and that the policies and procedures have been implemented.

Compliance Requirements

i. Staff (EMO/CMO) and others on duty are trained on the SOPs related to care of emergency patients evidenced through attendance record
ii. Evidence of training of staff on BLS, ACLS, ATLS and ALSO etc.
iii. Relevant staff is familiar with the policies and procedures pertaining to the emergency care
iv. Evidence that the procedures have been implemented

8- Commensurate with the triage process of initial assessment

Assessment

	Compliance Requirements	Evidence
i.	Relevant staff is familiar with the policies pertaining to the emergency care	Document Review
ii.	Evidence of staff training on the SOPs related to care of emergency patients	Document Review
v.	Evidence regarding implementation of procedures	Document Review

Scoring

- If the above requirements including consultant on-site are complied, then score as **fully met.**
- If all the above requirements are complied, except that the consultant staff is available on call and not on site, then score as **partially met.**
- If compliance is not as above, then score as **not met.**

Ind. 20 Admission or discharge to home or transfer to another organization is documented

Survey Process

Review a sample of at least 10 medical records, files or other documentation (emergency services log book) of patients who were treated in the Emergency Department. Observe the records and determine the discharge process. Review the advice and information provided to the patient or other clinician or treatment facility and determine if it is adequate to ensure support, recovery, ongoing treatment and follow-up that is clinically required.

Compliance Requirements

i. Record of the patient admitted, discharged to home or transferred/ referred to another organization has complete information regarding:

a. Admission
   - i. Time and date
   - ii. Department where admitted

b. Discharge
   - i. Time and date
   - ii. Condition at time of discharge
   - iii. Follow-up advice

c. Referral/ Transfer
   - i. Reason of transfer/referral
   - ii. Time and date
   - iii. Name of receiving hospital

d. Left against medical advice
   - i. Time and date of noticing absence of patient

e. Discharged on request
   - i. Time and date
   - ii. Signed statement of patient/attendant

f. Left without being seen
   - i. Time and date of noticing absence of patient

g. Death
   i. Death certificate containing date, time, reason and handing over of dead body
h. Received dead
I. Time and date

Assessment

	Compliance Requirements	Evidence
i.	Patient record contains complete information	Document Review

Scoring

- If this is 100 percent documented as above, then score as **fully met.**
- If only 1-2 cases fail to meet this requirement, then score as **partially met.**
- If 3 or more of the cases reviewed do not document this, then score as **not met.**

Standard 4. COP-2:

Policies and procedures define rational use of blood and blood products

Intent Statement

Use of blood and blood products is of critical importance in the hospital settings. This standard has therefore, been added for the safety pf patients and requires the policies and procedures to define rational use of blood and blood products. To achieve this, it requires the transfusion services to be governed by the documented policies and procedures prescribed under the applicable laws and regulations. These policies and procedures need to be followed in letter and spirit while transfusing blood and blood products. The standard further require taking an Informed consent for donation and transfusion of blood and blood products and training the staff members to implement the policies. The standard also require identifying and undertaking analysis of the transfusion reactions if nay, for future guidance and implementation of preventive and corrective actions.

Ind. 21 Documented policies and procedures are used to guide rational use of blood and blood products

Survey Process

Review the policies and procedures/SOPs of the BEs/HCEs that should cover processes related to 1. Donor screening, 2. Processing of blood, 3. Storage, perform compatibility tests before issuance of blood and blood components, distribution and transport for transfusion 4. Administration /use of blood and blood products, 5. Identification and analysis of real or suspected transfusion reactions in the donor and the recipient, 6. Disposal of blood and related products and 7. Record keeping for traceability of processes/actions at all steps in the blood chain.The surveyors should check availability of the entire set of SOPs/Guidelines but blood service provision will be checked only as per scope of services being portrayed and rendered. This is a significant patient safety issue.

Compliance Requirements

i. Copies of documented policies providing Guidelines for rational use of blood and blood products

ii. Evidence that the SOPs and processes of the BEs/ HBBs cover the following /applicable legal requirements and are followed:

a. Donor screening for blood donations, testing/ collection
b. Blood Processing
c. Storage of blood, perform compatibility tests before issuance of blood and blood components, distribution and transport for transfusion,
d. Administration /use of blood and blood products
e. Identification and analysis of real or suspected transfusion reactions in the donor and the recipient,
f. Disposal of blood and related products and
g. Record keeping for traceability of processes/actions at all steps in the blood chain.

Note: Blood service provision at the HCEs will be checked only as per scope of services portrayed and rendered but SOPs for the entire system should be available.

Assessment

	Compliance Requirements	Evidence
i.	Copies of documented policies providing relevant Guidelines	Document Review
ii.	SOPs covering relevant processes	Document Review
iii.	Evidence that SOPs are followed	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 22 The transfusion services are governed by the applicable laws and regulations

Survey Process

The surveyors need to be aware of the applicable laws and regulations on safe blood transfusion services[9] . This is surveyed by reviewing documentation such as copies of the current legislation and compliance requirements, list of range of services relevant to the blood establishment (blood centre or hospital blood bank), inspection report by PBTA, etc. and interviews with the staff, and observation. This includes an observable mechanism of traceability to ensure that only blood and blood products derived under the legal provisions/SOPs are provided to the patients. This is a significant patient safety issue.

Compliance Requirements

i. The Blood Establishment[10] functions to provide the blood services as specified in the applicable laws / regulations and the relevant SOPs

ii. Teaching Hospitals should have 24/7 operational Blood Center / Hospital Blood Bank as required under the Regulations prescribed for Medical and Dental Institutions by the PM&DC in 2012[11]

iii. All hospitals where, surgeries and or C-EmOC services are performed and the HCEs where blood transfusions are performed shall have at least an in house "hospital blood bank" capable of performing minimum functions as specified in the Act[12] or either of the following requirements and mechanism of traceability to ensure that only blood and blood products derived under the legal provisions/SOPs are provided to the patients:

   a. Valid License issued by the PBTA in respect of the Hospital Blood Bank
   b. MOU with the Licensed Blood Establishment (blood centre or hospital blood bank) vetted by PBTA
   c. Receipt of the fee paid to PBTA for vetting of the MOU with the Licensed Blood Establishment

iv. Adequate facilities for temporary storage of blood received from licensed Blood Establishment

9- Punjab Blood Transfusion Safety ACT 2016 and the Guidelines issued by Punjab Blood Transfusion Authority.
10- Includes Blood Center or Hospital Blood Bank or both.
11- SRO 26(KE)/2012 dated 05/01/2012.
12- Blood Center (BC) as defined under Section 2 (e) means any structure or a body which manufactures blood and blood components; and, performs collection, testing, processing, storage, and distribution of blood and blood components to the hospital blood banks. Section 10 of the Act describes the Functions of the Blood Center.
Hospital Blood Bank (HBB) as defined in Section 2 (n) means a hospital unit which receives and stores screened blood and blood components received from a blood center, performs compatibility testing and issues blood and blood components for clinical use. Section 11 of the Act describes the Functions of the Hospital Blood Bank.
Blood Establishment (BE) as defined vide Section 2 (g) of the Act means any facility carrying out one or more of the processes in the blood transfusion chain.
Establishing a Hospital Blood Bank is a mandatory requirement for HCEs where C-EmonC services, surgeries and other HCEs where blood transfusions are performed as prescribed in Ind. 21. Teaching Hospitals, Cat-I HCEs and Cat-IIA HCEs are expected to establish BCs in addition to HBBs. Carefully considered exception of not having a HBB by Cat-IIB and Cat-IIC HCEs may be entertained provided that the HCE undertaking blood transfusion without having a HBB, maintains documented evidence that the transfused blood and blood product is issued by a BC/HBB licensed by PBTA and with the understanding that the issued blood will be taken back for separate storage at the licensed BC/HBB to avoid wastage while complying all legal requirements particularly ensuring organizational responsibilities of each party towards end to end traceability and maintaining the Cold Chain during transportation of blood.

Assessment

	Compliance Requirements	Evidence	
i.	Copies of the relevant SOPs /PBTA documents	Document Review	
ii.	Applicable laws being employed by all staff	Document Review	
iii.	Mechanism to provide for traceability that only blood and blood products derived under the legal provisions/SOPs are provided to the patients	Document Review	Observation
iv.	Temporary storage of blood received from licensed Blood Establishment		

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 23 Informed consent is obtained for donation and transfusion of blood and blood products.

Survey Process

While visiting the blood bank identify the names of at least 10 patients who have received blood. Then review the medical records of these patients to determine if there is documented 'informed consent' and if the consent adequately informs the patient. If the hospital processes donors, also review a sample of at least 5 people to determine if the donors gave informed consent and this was appropriate for the individuals concerned. Informed consent must be signed form designed to ensure that people of ALL backgrounds truly understand the risks and options involved and the evidence provided must clearly support this. This includes information and education of the patient and their family, when present. In exceptional cases, when the patient is not capable of giving consent, informed consent can be either a signed form or a note by the physician.

Compliance Requirements

i. Informed consent from all donors as well as recipients as applicable

ii. Informed consent signed by the donor and recipient on the prescribed form/ format except in cases when the recipient is an emergency /unconscious patient without family or guardians present at the time, a signed form or a note by the physician.

Assessment

	Compliance Requirements	Evidence
i.	Informed consent in all records of donors as well as recipients as applicable	Document Review
ii.	A note by the treating physician in cases when the recipient is an emergency /unconscious patient without guardian	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 24 Staff members are trained to implement the policies

Survey Process

While visiting the blood bank, check that staff members are aware of the policy and procedure related to the working of blood transfusion services. Review the records to look for the evidence of training of the staff on the documented policies and procedures and discuss with the staff regarding compliance requirements of the same and.

Compliance Requirements

i. Evidence of training of the staff on the Policies and procedures present in the blood bank
ii. Staff awareness regarding the Policies and procedures /SOPs
iii. Evidence that the policies and procedures are practiced

Assessment

	Compliance Requirements	Evidence		
i.	Staff trained to practice the Policies and procedures	Document Review		
ii.	Awareness of the staff regarding policies and procedures	Interview		
iii.	Evidence of compliance with the Policies and procedures	Document Review	Observation	Interview

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 25 Transfusion reactions are analysed for preventive and corrective actions

Survey Process

Ask for documentation that reports transfusion reactions. Evaluate whether the documentation demonstrates adequate analysis and remedial actions. In the case where no reactions are reported as occurring[13], the surveyors should evaluate whether there are adequate and clearly written procedures for analysis and remedial action if a reaction does occur. Check that staff members are aware of the reporting process.

Compliance Requirements

i. Record of identification and analysis of blood transfusion reactions
ii. SOPs for analysis and remedial action/s
iii. Awareness of staff regarding reporting requirements as per statutes
iv. Evidence that the Authority was informed as per Section 13 of Punjab Blood Transfusion Safety ACT 2016"

"Information to the Authority – A blood establishment shall immediately inform the Authority, in the prescribed manner, of any serious adverse event or serious adverse reaction."

13- This would be highly unlikely.

Assessment

	Compliance Requirements	Evidence
i.	Record of identification of blood transfusion reactions	Document Review
ii.	SOPs for analysis of transfusion reactions and remedial action/s	Document Review
iii.	Awareness of staff regarding statutory reporting requirements	Interview
iv.	Evidence that the Authority was informed as applicable	Document Review

Scoring

- If the above stated requirements are complied, then score as **fully met.**
- If the above stated requirements are not complied, then score as **not met.**

Standard 5. COP-3:

Policies and procedures guide the care of high risk obstetrical patients

Intent Statement

This standard has been prescribed for ensuring that policies and procedures guide for delivering safe care to the cases of high risk obstetrical patients. The standard requires the HCEs to define high-risk obstetric cases and display whether high-risk obstetric cases can be cared for or not. In cases where high-risk obstetric cases are treated the person/s providing care to such cases are competent. The standard also requires that assessment of the High-risk obstetric patients also include assessment of maternal nutritional status. The organization caring for high risk obstetric cases is should have the facilities and technically competent staff to take care of neonates of such cases. No treatment should be administered unless the identity of the patient can be guaranteed.

Ind. 26 The organization defines and displays whether high-risk obstetric cases can be cared for or not

Survey Process

Since many patients will not know if they are high risk or not, it is important that the hospital has informed its obstetrical patients of the definition of high risk obstetrical case and its capability to provide services for these women. The second important point is that the hospital should inform those practitioners and facilities that might refer such patients, about the hospital's capability to provide care to high-risk obstetric cases. This should be done by using feasible means of communication in any combination. There must be documentation of the communication made with the practitioners and facilities.

Compliance Requirements

i. High risk obstetric cases defined
ii. Displaying the list of high risk obstetric cases that can be managed at the HCE
iii. Informing the hospitals own obstetric patients by all possible means about its capability to provide services for the high – risk obstetric cases
iv. Communication to its referring practitioners and other facilities by all possible means of communication including boards, banner/s, brochures, website and individual letters etc.

Assessment

	Compliance Requirements	Evidence	
I.	High risk obstetric cases defined	Document Review	
ii.	Displayed list of high risk obstetric cases that can be managed at the HCE	Document Review	
iii.	Informing the hospitals own obstetric patients about its capability to provide services for the high –risk obstetric cases	Document Review	observation
iv.	Communication to its referring practitioners and other facilities	Document Review	Observation

Scoring

- If the hospital has informed its own obstetric patients and its referring practitioners and other facilities of its capability to care for high-risk obstetric cases, then score as **fully met.**
- If the hospital has informed its own patients, but not referring providers or facilities, then score as **partially met.**

- If the hospital has neither informed its own patients or referring providers or facilities, then score as **not met.**

Ind. 27 Persons caring for high-risk obstetric cases are competent

Survey Process

Surveyors should look for the availability of specialized care[14] / services of specialist on 24 hours/day, 7 days/week basis, who is fully qualified in obstetrics and who has advanced training in high-risk obstetrics and documented experience[15]. In addition, there should be evidence that the nursing staff who care for such patients have recognized qualifications and documented experience. There should also be arrangements for 24/7 medical and nursing coverage for the patients admitted in the HCE.

Compliance Requirements

i. Availability of specialized care on 24 hours/day, 7 days/week through displayed non duty roster:
   a. A qualified obstetrician.
   b. Preferably having advanced training in high-risk obstetrics.
   c. Documented experience.
ii. 24/7 medical and nursing coverage for the patients admitted in the HCE.
iii. Nursing staff who care for such patients have:
   a. recognized qualifications
   b. documented experience.
iv. Duty roster showing 24/7 availability of specialized care in Gynae/Obs
v. Duty roster showing 24/7 availability of qualified medical and nursing staff
vi. Credentials of the gynaecologists (at least 3 gynecologists for teaching hospitals and 2 for other hospitals) and other staff involved in the care of high-risk obstetric patients having appropriate qualifications and experience for provision of specialized care on 24/7 basis

Assessment

	Compliance Requirements	Evidence	
i.	Availability of specialized care in Gynae/Obs on 24 /7 basis	Document Review	
Ii	24/7 medical coverage	Document Review	Observation
ii.	Nursing staff having qualifications and documented experience	Interview	Document Review
iii.	Duty roster showing 24/7 availability of specialized care in Gynae / Obstetric and qualified nursing staff	Observation	
iv.	Credentials of the staff	Observation	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If there is any non-conformance to the above, then score as **not met.**

14- This is the absolute minimum to provide 24hrs, 7 days per week service based on 3 shifts per day and 270 productive workdays per employee per year. Hospital management is expected to employ additional specialists according to the workload.

15- The Job Descriptions and Performance Evaluation Criteria for Medical, Nursing and Paramedical Staff, Punjab Devolved Social Services Programme, Govt. of the Punjab, 2008-09.

Ind. 28 High-risk obstetric patients are also assessed for maternal nutrition status

Survey Process

This will be surveyed by review of a sample of at least 5 medical records of high-risk obstetric patients that should reflect evidence in respect of assessment and advice regarding corrective measures on the nutritional status of the patients if needed.

Compliance Requirements

i. Documented nutritional assessments
ii. Advice regarding corrective measures on the nutritional status of the patients if needed and follow up advice

Assessment

	Compliance Requirements	Evidence
i.	Nutritional assessments documented	Document Review
ii.	Evidence regarding corrective measures and follow up on advice regarding nutritional status as needed	Document Review

Scoring

- If ALL records document assessment of the patient's nutritional status (including corrective measures if needed), then score as **fully met.**
- If only one medical record does not document this but it is clinically obvious that the patient had good nutritional status, then score as **partially met.**
- If more than one record fails to document the patient's nutritional status, then score as **not met.**

Ind. 29 The organization caring for high risk obstetric cases has the facilities and technically competent staff to take care of neonates of such cases

Survey Process

Although this may require some surveyor judgment, the minimum essential equipment in working order and technically competent medical and nursing staff for using it and providing care to such neonates should be available.

Compliance Requirements

i. Availability of the following essential items/ equipment:
   - Emergency resuscitation drugs
   - Neonatal resuscitation drugs
   - Ambu bag
   - Neo-natal face mask
   - Neo-natal laryngoscope
   - A selection of Neo-natal Endo tracheal tubes
   - Oxygen supply
   - Suction machine
   - Baby warmer

- Incubator
- Infusion pump/micro burette
- Umbilical artery cannulation tray (in case of in house neonatology unit)
- Exchange transfusion tray (in case of in house neonatology unit)

ii. Presence of Pediatrician/neonatologist (as per duty roster/requirement) and other qualified and competent nursing staff trained in neonatal resuscitation

Assessment

	Compliance Requirements	Evidence
i.	Availability of essential items and equipment in working order	Document Review
ii.	Availability of qualified staff trained in neonatal resuscitation	Document Review

Scoring

- If ALL the equipment listed above is present and in good working order, then score as **fully met.**
- If ALL the required equipment and supplies defined above are not present, but the survey team agrees that the hospital has safely defined alternatives, then score as **partially met.**
- If the survey team agrees that any critical equipment or supplies are not available, then score as **not met.**

Ind. 30 No treatment should be administered unless the identity of the patient can be guaranteed

Survey Process

The surveyor should identify a form of safe patient identification system[16] and confirm that the ALL treatments and therapies are administered after correctly confirming the identity of the patient/s. However, care should be exercised and exceptions accepted in case of emergency patients requiring life-saving drugs/therapies, denial of which may create liabilities under other laws.

Compliance Requirements

i. Use of identity tag in newborn and the mothers containing:
   a. Name of the patient/baby of……..
   b. MR Number

ii. The staff is familiar with the practices of confirming identity of patient before administering the treatment

Assessment

	Compliance Requirements	Evidence	
i.	Use of identity tag	Document Review	Observation
ii.	Patients' Files	Document Review	
iii.	Staff Interview	Document Review	

16- For ALL patients the system employed must be permanently with the patient and fail-safe.

Scoring

- If the identification of the patient is clearly observable and fail safe for ALL patients and staff confirm identity before administering any treatment, then score as **fully met.**
- If a fail- safe method of identification is present and staff does not consistently check the identity before treatment, then score as **partially met.**
- If there is no fail-safe system of identification, then score as **not met.**

Standard 6. COP-4:
Policies and procedures guide the administration of anaesthesia

Intent Statement
This standard has been prescribed for ensuring that there are documented policies and procedures that guide the administration of anesthesia for patient safety. The documented SOPs should cover the administration of anesthesia, pre-anaesthetic assessment by a qualified individual, formulation of an anaesthetic plan for each patient, which is documented. It is also required that informed consent for administration of anesthesia is obtained by a qualified member of the anaesthetic team and that an immediate pre-operative (pre-induction) re-evaluation is documented. The SOPs should also cover during anesthesia monitoring that should include regular and periodic recording of required signs. It should also be ensured that no anaesthetic is administered unless the identity of the patient can be guaranteed and all adverse anesthesia events when occur are recorded and monitored. The SOPs should ensure that post-anaesthetic status of each patient is monitored and documented. A qualified individual should apply defined criteria to transfer the patient from the recovery area.

Ind. 31 There is a documented policy and procedure for the administration of anaesthesia

Survey Process
The surveyor should look for the SOPs based on policies that should cover at least the pre-anaesthesia evaluation, Assignment of an anaesthesia risk then score (such as an ASA[17] then score), documentation requirements during anaesthesia, identification and recording of any complications, post-anaesthesia monitoring requirements, and criteria for shifting from anaesthesia care.

Compliance Requirements
Availability of documented policies covering SOPS for:

i. Staff responsibilities in provision of anesthesia care
ii. Safe handling and storage of anesthetic medicines and agents
iii. Equipment and maintenance
iv. Pre-anesthesia assessment (in line with the ASA scoring)
v. Pre-induction re-evaluation
vi. Documented intra-operative monitoring of the anesthetized patients
vii. Recording of any complication/ adverse anesthesia events
viii. Post anesthesia monitoring
ix. Criteria for shifting of patients from anesthesia care

Assessment

	Compliance Requirements	Evidence	
i.	Staff responsibilities in provision of anesthesia care	Document Review	Interview
ii	Safe handling and storage of anesthetic medicines and agents	Observation	Interview

17- Physical Status Classification and Scoring by the American Society of Anaesthesiologists.

iii	Equipment and maintenance	Observation	Document Review
iv	Pre-anesthesia assessment (in line with ASA scoring)	Document Review	
V	Pre-induction re-evaluation	Document Review	
vi	Documented intra-operative monitoring of the anesthetized patient	Document Review	
vii	Recording of any complication /adverse anesthesia events	Document Review	
viii	Post anesthesia monitoring	Observation	Document Review
ix	Criteria for shifting of patients from anesthesia care	Observation	Document Review

Scoring

- If there are policies and procedures that cover ALL the above 9 requirements, then score as **fully met.**
- If there are policies and procedures for ALL the 9 requirements, but only 8 out of the 10 interviewed staff members are aware of the same, then score as **partially met.**
- If either there are no policies and procedures, or if it does not cover all the above components or if less than 8 out of 10 interviewed staff members are aware of the same, then score as **not met**.

Ind. 32 ALL patients for anaesthesia have a pre-anaesthetic assessment by a qualified individual

Survey Process

Review a sample of at least 10 medical records of patients who underwent anesthesia. Determine if there is a documented pre-anaesthetic assessment. An anesthetist should do the assessment unless the hospital has identified another specialist / professional qualified to do the pre-anesthesia assessment.

Compliance Requirements

i. Availability of credentials / authorization of professional/s performing pre-anesthesia assessments

ii. Pre-anesthesia assessment documented by the authorized professionals in all patients undergone surgery

Assessment

	Compliance Requirements	Evidence
i.	Credentials / authorization of professional/s performing pre-anesthesia assessments	Document Review
ii.	Documentation Pre-anesthesia assessment	Document Review

Scoring

- If there is a pre-anesthesia assessment by an anesthetist or qualified doctor with documented appropriate training for ALL patients, then score as **fully met.**
- Since this is an important patient safety issue, if ANY medical record does not include a documented pre-anesthesia assessment, then score as **not met.**

Ind. 33 The pre-anaesthesia assessment results in formulation of an anaesthetic plan for each patient, which is documented

Survey Process

This standard is intended to validate that the pre-anesthesia assessment identifies any risks and determines the appropriate anaesthetic approach (for example, a patient with multiple back injuries or surgeries might not be a safe candidate for spinal anesthesia or a patient with chronic obstructive pulmonary disease might not be a safe candidate for inhalation anesthesia). Review a selection of at least 10 medical records of patients who underwent anesthesia to determine if the anaesthetic plan matches the pre-anesthesia assessment.

Compliance Requirements

i. Documented anesthesia plan for the patients who underwent anesthesia / surgery
ii. Anesthesia plan is based on pre anesthesia assessment

Assessment

	Compliance Requirements	Evidence
i.	Documented anesthesia plan	Document Review
ii.	Anesthesia plan based pre-anesthesia assessments	Document Review

Scoring

- If the anesthetic plan reflects and matches the findings of the pre- anesthesia assessment, then score as **fully met.**
- If a majority of the survey team agrees that there are significant discrepancies between the pre-anesthesia assessment and the anaesthetic administered, then score as **not met.**

Ind. 34 An immediate pre-operative (pre-induction) re-evaluation is documented

Survey Process

The intent of this indicator is to compare the findings and management plan in the formal pre-anesthesia assessment with the immediate pre-operative anaesthetic assessment and to see if the management of the patient is changed if required. The immediate pre-anesthesia repeat evaluation should be documented on the anesthesia record that becomes part of the patient's medical record. Review a sample of at least 10 medical records of patients who underwent anesthesia to determine that Pre-induction re-evaluation was done and documented.

Compliance Requirements

i. Pre-induction re-evaluation documentation including at least the record of vital signs in the patients undergoing surgery is practiced
ii. Evidence that the management of the patient was changed if required by the immediate pre-operative anaesthetic assessment

Assessment

	Compliance Requirements	Evidence
I.	Pre-induction re-evaluation documentation	Document Review
ii.	Evidence that the patient management was changed if required by the immediate pre-operative/ pre- anaesthetic assessment	Document Review

Scoring

- If the immediate pre-induction re-evaluation is documented in ALL records, then score as **fully met.**
- If the immediate pre-induction re-evaluation is NOT documented in ALL records, then score as **not met.**

Ind. 35 Informed consent for administration of anaesthesia is obtained by a qualified member of the anaesthetic team

Survey Process

Reviewing the same records as in **Ind 32**, determine if ALL patients who underwent anesthesia have a documented informed consent[18].

Compliance Requirements

i. Availability of informed consent signed by the patient/attendant and the doctor from anesthesia department in a sample of at least 10 files of patients undergone surgery

ii. Evidence that the contents of the consent accommodate ALL patient levels of understanding

Assessment

	Compliance Requirements	Evidence
i.	Documented informed consent	Document Review
ii.	Contents of the consent accommodate ALL patient levels of understanding	Document Review

Scoring

- If ALL records contain documentation of informed consent, then score as **fully met.**
- Since this is a significant medico-legal issue, if ANY record does not contain documentation of informed consent, then score as **not met.**

Ind. 36 During anaesthesia, monitoring includes regular and periodic recording of required signs

Survey Process

The compliance of this indicator is surveyed by observation and review of the medical record. While visiting the operating theatre look for the presence and full functional equipment that supports ALL the requirements of monitoring during anaesthesia as prescribed in this indicator. The medical record of the patient who underwent anaesthesia has documented during anaesthesia monitoring.

18- Informed consent must truly be appropriate for each patient and include reference to the associated risks involved

Compliance Requirements

I. Fully functional equipment that supports ALL the requirements of monitoring during anesthesia including the following:
   a. Heart rate,
   b. Cardiac rhythm,
   c. Blood pressure,
   d. Respiratory rate,
   e. Oxygen saturation,
   f. Airway security and patency

ii. Reviewed patients' record has documented during anesthesia monitoring

Assessment

	Compliance Requirements	Evidence
i.	Fully functional equipment that supports ALL the requirements of monitoring during anesthesia	Observation
ii.	Documented during anesthesia monitoring in the reviewed patients' record	Document Review

Scoring

- If the above monitoring requirements are complied, then score as **fully met.**
- If the above monitoring requirements are not complied, then score as **not met.**

Ind. 37 Informed consent for administration of anaesthesia is obtained by a qualified member of the anaesthetic team

Survey Process

The surveyor should identify a form of safe patient ID system and confirm in a sample of at least 10 patients' record that the administration of anesthesia is preceded by confirming the identity of the patient with that checklist.

Compliance Requirements

i. A fail - safe system for confirming identity of patients prior to induction of anaesthesia

ii. The staff is conversant with the system of confirming identity of patients prior to induction of anaesthesia

iii. Filled in checklist for confirming the identity of all patients reviewed record who had undergone surgery

Assessment

	Compliance Requirements	Evidence
i.	A fail - safe system for confirming identity of patients prior to induction of anaesthesia	Document Review
ii.	Staff conversant with the system of confirming identity of patients	Interview
iii.	Filled in checklists	Document Review

19- For ALL patients the system employed must be permanently with the patient and fail-safe.

Scoring:

- If the identification of the patient is clearly observable and fail safe for ALL patients and staff confirm identity prior to induction, then score as **fully met.**
- If there is no fail safe system of identification or any patient's identity is not confirmed, then score as **not met.**

Ind. 38 Each patient's post-anaesthetic status is monitored and documented

Survey Process

Review the medical records of at least 10 patients in the recovery area or who have been in the post-operative recovery area previously. There should be documented evidence of post-anaesthetic monitoring that includes at least; the blood pressure, pulse rate, respiratory status, airway security and patency, level of consciousness (response to verbal commands/pain stimuli), and pain. The medical records should have documented evidence of post-anaesthetic monitoring.

Compliance Requirements

i. The reviewed medical records reflect post-anaesthetic monitoring of at least the following:
   a. Heart rate
   b. Blood pressure
   c. Respiratory rate
   d. Airway security and patency
   e. Level of consciousness (response to verbal commands/pain stimuli)
   f. Pain

Assessment

	Compliance Requirements	Evidence
i.	Documented post-anaesthetic monitoring	Document Review

Scoring

- If ALL records document compliance of the above requirements, then score as f**ully met.**
- If only one record does not document compliance of the above requirements, then score as **partially met.**
- If more than one record does not document ALL the requirements, then score as **not met.**

Ind. 39 A qualified individual applies defined criteria to transfer the patient from the recovery area

Survey Process

Look first for the written criteria for discharge from the post-operative recovery area. Then while reviewing the 10 records as in previous Indicators, determine if an anesthetist or other qualified person with appropriate training[20] has done so.

20- This may include a medical graduate who has received documented training and experience

Compliance Requirements

i. Documentation of shifting notes from the recovery area in all files of patients undergone surgery
ii. Evidence that shifting notes are documented by qualified individual

Assessment

	Compliance Requirements	Evidence
i.	Documented shifting notes	Document Review
Ii	shifting notes are documented by qualified individual	

Scoring

- If there is an observable documented process that ensures the safe transfer of post anaesthetic patients, then score as **fully met.**
- If the staff is unaware of criteria for the safe transfer of post anesthetic patients or f the same is not practiced, then score as **not met.**

Ind. 40 All adverse anaesthesia events are recorded and monitored

Survey Process

Ask for the report(s) of any anesthesia related adverse events. Review the analysis and any corrective action that is specified. If there have been no adverse events, which is unlikely unless a new service, validate that there is a process to identify the event and to intensively analyze it, including recommended corrective actions.

Compliance Requirements

i. Monitoring and recording of:
   a. Adverse anesthesia events
   b. Analysis of Adverse anesthesia events
   c. Recommendations for avoiding such in future
ii. Follow up from anaesthesia services for corrective actions

Assessment

	Compliance Requirements	Evidence
I.	Recording and monitoring of Adverse anesthesia events	Document Review
ii.	Evidence that the Adverse anesthesia events are monitored	Document Review
iii.	Corrective actions for avoiding such Adverse anesthesia events	Document Review

Scoring

- If the above requirements are complied, then score as met OR if there has been no adverse anesthesia event but there is a process to identify such events and also a process to analyze those, then score as **fully met.**
- If there was an anaesthetic related adverse occurrence and it was not either reported or analyzed, or if there is no process to analyze an adverse event if it were to occur, then score as **not met.**

Standard 7. COP-5:

Policies and procedures guide the care of patients undergoing surgical procedures

Intent Statement

The intent of this standard is to ensure that the hospital has policies and procedures that guide the care of patients undergoing surgical procedures, for patient and care provider's safety. The standard therefore requires the HCEs to document the surgery-related policies and procedures that should cover a pre-operative assessment, documenting a provisional diagnosis for surgical patients prior to surgery and obtaining an informed consent by a qualified medical member of the surgical team prior to the procedure. There should be documented policies and procedures to be practiced to prevent adverse events like wrong site, wrong patient and wrong surgery. The policies and procedures should also ensure that only the persons qualified and permitted by law perform the procedures that they are entitled to perform. The policies should also provide SOPs for documenting a brief operative note by the surgeon or a doctor in the surgical team and to document the post-operative plan of care prior to transferring the patient out of the recovery area. It is also required that a quality assurance programme including surveillance of the operation theatre environment and monitoring of surgical site infection rates is followed for the surgical services.

Ind. 41 The surgery-related policies and procedures are documented

Survey Process

There are written policies that include pre-operative, intra-operative and postoperative care. Staff members are aware of the policies and procedures and their applicability.

Compliance Requirements

i. Documented surgery-related policies and procedures covering the following:
   a. SOPs about pre-operative assessment
   b. Pre-operative provisional diagnosis
   c. Obtaining informed consent by a qualified medical member of the surgical team prior to the procedure
   d. SOPs for prevention of adverse events like; wrong patient, wrong surgery, or wrong site
   e. SOPs regarding writing operative note by the surgeon or a doctor of the surgical team
   f. Documenting Post-operative Care plan prior to transferring the patient out of the recovery area

ii. Staff members are aware of the policies and procedures and their applicability

Assessment

	Compliance Requirements	Evidence	
i.	Documented SOPs	Document Review	
ii.	Staff awareness about the policies and procedures and their applicability	Observation	Interview

Scoring

- If there are written policies for pre-operative, intra operative and postoperative care and the staff is aware, of the policies and their applicability, then score as **fully met.**

- If there are policies, but only 8 out of 10 interviewed staff are aware of the policy, then score as **partially met.**
- If there are no, or insufficient policies or if more than 8 out of 10 interviewed staff is not aware of the same, then score as **not met.**

Ind. 42 Surgical patients have a pre-operative assessment and a provisional diagnosis documented prior to surgery

Survey Process

Review a sample of 10 medical records of patients who underwent surgery to determine if a pre-operative assessment including the history and physical examination by the surgeon or pre-operative note is present and that a pre-operative provisional diagnosis was documented.

Compliance Requirements

i. Patients record files contain the following:
   a. Pre-operative assessment (including clinical history and Physical Examination)
   b. Provisional diagnosis.
   c. Operation plan.

Assessment

	Compliance Requirements	Evidence
i.	The patents' record containing pre-operative assessment i.e. history and physical examination or pre-operative note	Document Review
ii.	The pre-operative assessment also includes provisional diagnosis	Document Review

Scoring

- If there is a pre-operative history and physical examination or a pre-operative note by the surgeon that includes a provisional pre-operative diagnosis, then score as **fully met.**
- If there is a pre- operative history and physical examination or surgeon's note, but pre-operative provisional diagnosis is not documented, then score as **partially met.**
- If there is no pre- operative history and physical examination or surgeon's note, then score as **not met.**

Ind. 43 An informed consent is obtained by a qualified medical member of the surgical team prior to the procedure

Survey Process

Review the same 10 records to determine if an informed consent was obtained by a qualified medical member of the surgical team prior to the procedure and documented in the medical record. The informed consent must include evidence that the patient was educated/informed. This is surveyed in the same way as policies and procedures guide for the administration of anaesthesia.

Compliance Requirements

i. Informed consent documented prior to surgery
ii. Informed consent obtained by a qualified medical member of the surgical team
iii. Informed consent has the evidence that the patient was educated/informed

	Compliance Requirements	Evidence
i.	Informed consent documented prior to surgery	Document Review
ii.	Informed consent obtained by a qualified member of the surgical team	Document Review
iii.	Informed consent has the evidence that the patient was educated/informed	Document Review

Scoring

- If ALL the medical records document an informed consent (a signed form or a note by the physician), then score as **fully met.**
- Since this is a significant medico-legal issue, if ANY record does not have documentation of informed consent, then score as **not met.**

Ind. 44 Documented policies and procedures exist to prevent adverse events like wrong site, wrong patient and wrong surgery

Survey Process

This is a critically important patient safety issue. Look for the implementation and documentation of processes of marking the surgical site and side in at least 10 medical records of patients who had surgery, when there is the possibility of confusion about the side. Also look for a pre-operative checklist to ensure that ALL documents like X-rays and diagnostic /medical reports, etc. and the needed equipment is available. The checklist should also confirm that "time out" is called prior to induction of anaesthesia to ensure that ALL members of the surgical team are in agreement that this is the correct patient; this is the correct procedure for this patient, and that this is the correct side (if relevant).

Compliance Requirements

I. The checked medical records contain checklist as evidence that the processes of marking the surgical site and side (as applicable) was implemented and documented

ii. The checked medical records of patients who had undergone surgery have evidence of calling "time out" ensuring agreement of ALL members of the surgical team that:

- a. This is the correct patient
- b. This is the correct procedure for this patient
- c. This is the correct site and side (if relevant)

iii. The medical records also contain checklist confirming that ALL documents like X-rays and medical /diagnostic reports, etc. and the needed equipment is available

Assessment

	Compliance Requirements	Evidence
i.	Checking of patient files as above	Document Review

Scoring

- If ALL requirements (marking side / site when relevant, use of a checklist, and a "timeout" recorded) are used and documented in the medical record, then score as **fully met.**
- If any of the above requirements are not documented in the medical record, then score as **not met.**

Ind. 45 Persons qualified by law are permitted to perform the procedures that they are entitled to perform

Survey Process

The surveyors should check 10 patient files undergone surgery and look for documents that demonstrate a process to validate the qualifications, experience and registration status of surgeons to ensure that they are legally permitted, and competent to perform specific procedures. The scope of clinical practice shall be defined and documented for all surgeons and performance monitored through the recording of adverse outcomes and peer review.

Compliance Requirements

i. Only the persons who are qualified and legally allowed are authorized to perform the specific procedures which is evident in the record of patients having undergone surgery by entries of:

a. Name of the surgeon.
b. Name/s of assistant/team.
c. Name of anesthetist.

ii. This also implies that the specialists/ consultants employed in the public sector do not perform surgeries /procedures /practice at private HCEs during official working hours

Assessment

	Compliance Requirements	Evidence
I.	The persons performing the specific procedures are qualified and legally allowed to do so	Document Review
ii	The specialists/ consultants employed in the public sector do not perform surgeries /procedures / practice at private HCEs during official working hours	Observation

Scoring

- If there is a recognized process to validate that the professionals authorized (currently registered) and competent (based on academic credentials, experience, training and internal recognition) to perform the procedure are conducting the same, then score as **fully met.**
- If there is no process to validate the authorization or competence to perform the procedure(s), then score as **not met.**

Ind. 46 A brief operative note is documented by the surgeon or a doctor in the surgical team prior to transferring the patient out of the recovery area

Survey Process

Review the same 10 medical records picked earlier for checking. Determine if there is a documented operative note that was recorded prior to the patient being transferred from the recovery area. Also, while in the recovery area, review the medical records of patients who are about to be transferred out of the recovery area to determine if an operative note is documented in the medical record.

Compliance Requirements

i. Operation note endorsed prior to transfer of patient from recovery area including at least:

- Name of the surgeon
- Assistant/team

- Anesthetist
- Type of anesthesia
- Procedure performed
- Findings
- Any specimen removed for biopsy
- Blood loss/transfusion
- Any uneventful development
- Patient's condition at the conclusion of the procedure

Assessment

	Compliance Requirements	Evidence
i	Medical records contain operative notes	Document Review

Scoring

- If there is an operative note and it was documented in the medical record prior to transfer from the recovery area, then score as **fully met.**
- If there is either no operative note, or it was completed after the patient was transferred out of the recovery area, then score as **not met.**

Ind. 47 The operating surgeon or their surgical assisstant documents the post-operative plan of care

Survey Process

Review the 10 medical records as picked earlier for checking and validate that the surgeon (or their representative such as a surgical assistant) has written post-operative orders and care plan.

Compliance Requirements

i. Post-operative plan of care documented in patient's files undergone surgery include:
   a. Post-operative monitoring para meters and its frequency
   b. Medication orders
   c. Wound care
   d. Care of drain and catheters
   e. Patient's special positioning requirements
   f. Nutritional instructions
   g. Special referrals (physiotherapy and respiratory therapy)
   h. Fluid input/output record if applicable

il. Instructions regarding blood transfusion if required

	Compliance Requirements	Evidence
i.	Post-operative care plan and monitoring para meters/ frequency documented	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 48 A quality assurance programme is followed for the surgical services

Survey Process

Review any documentation of the quality assurance progarmme for surgical services that should require holding periodic meetings of the quality improvement committee or Surgical Department meeting or of research projects (if applicable) to ensure that the quality indicators of surgical care are being monitored. The plan should also require documenting the results of the surveillance activities and presenting the minutes of the meetings at the next relevant committee meeting for consideration and approval.

Compliance Requirements

i. There is Documented Quality Assurance Programme

ii. QA Programme covers holding periodic meetings of quality improvement committee/OT management committee or Surgical Department meeting for monitoring the quality indicators of Surgical Services and invasive procedures and is evident from minutes of meeting

Assessment

	Compliance Requirements	Evidence
i.	Documented QA Programme	Document Review
ii.	QA Programme cover periodic meetings of the quality improvement committee/OT management committee for monitoring of the Surgical Services and invasive procedures and is evident in minutes of meetin	Document Review

Scoring

- If there is evidence that the documented QA Programme for monitoring the quality indicators of Surgical Services and invasive procedures by surgical quality assurance committee with adequate composition of committee on monthly basis, then score as **fully met.**
- If there is evidence that the documented QA Programme for monitoring the quality indicators of Surgical Services and invasive procedures is monitored by surgical quality assurance committee with adequate composition of committee on quarterly basis, then score as **partially met.**
- If there is no QA Programme to monitor surgical care including all aspects of Surgical Services and invasive procedures, then score as **not met.**

Ind. 49 The surgical quality assurance programme includes surveillance of the operation theatre environment

Survey Process

The quality assurance programme for surgical services should review surveillance of the infection prevention and control, medical equipment maintenance, and cleaning of the theatres between cases. The results of these surveillance activities should be documented and placed for approval as minutes of the meetings at the next relevant committee meeting. Determine the action that arises from the reports is taken and determine if this is able to influence the rate of infection. This should be found in the minutes of an Infection Control Committee.

Compliance Requirements

I. The quality assurance programme for surgical services monitor the following:

a. Cleaning and disinfection of the medical equipment
b. Periodic Preventive maintenance and calibration of Equipment
c. Taking culture swabs from the following sites as per guidelines / as indicated:
   - Operation table
   - Floor and Walls
   - Instrument trolley
   - Air Conditioner Vent
   - Air
   - Operation Light
   - Anaesthesia machine

ii. Evidence of corrective actions as per surveillance report/s

Assessment

	Compliance Requirements	Evidence
i.	Record of cleaning and disinfection of OT between cases	Document Review
ii.	Cleaning and disinfection of the medical equipment	Document Review
iii.	Periodic Preventive maintenance and calibration of Equipment	Document Review
iv.	Surveillance of OT environment / taking culture swabs as per guidelines	Document Review
v.	Evidence of corrective actions	Document Review

Scoring

- If there is evidence that the safety and cleanliness of the operation theatre environment is evaluated, then score as **fully met.**
- If there is no surveillance of the operating theatre, then score as **not met.**

Ind. 50 The plan also includes monitoring of surgical site infection rates

Survey Process

This should be found in the minutes of an Infection Prevention and Control Committee. The surveyors should specifically look for evidence that the infection rates are physician, procedure, and room specific as the rates without organizing the data into categories are of little use. Determine the action that arises from the reports and determine if this is able to influence the rate of infection.

Compliance Requirements

i. SOPs to monitor surgical site infection rate
ii. Record of surgical site infection/s segregated into individual physicians, procedures and rooms
iii. Periodic analysis of the infection rates (on monthly basis) with evidence that remedial actions were initiated

Assessment

	Compliance Requirements	Evidence	
i.	SOPs to monitor surgical site infection rate	Observation	Document Review
ii.	Record of surgical site infection/s segregated into individual physicians, procedures and rooms	Document Review	
iii.	Periodic analysis on monthly basis of infection rates with documented remedial actions	Document Review	

Scoring

- If there is data about monitoring surgical site infections on monthly basis and it is segregated into individual physicians, procedures, and rooms, with evidence that remedial management has been initiated, then score as **fully met.**
- If there is data about monitoring surgical site infections on monthly basis, but only in the aggregate without specific analysis, then score as **partially met.**
- If there is no data about monitoring surgical site infections, then score as **not met.**

Functional Area: Management of Medication

Outline:
Standards: 3 (8-10)
Indicators: 21 (51-71) **(16 + 5)**

Standard 8

Prescription

- Documented Policies and Procedures
- Prescription Writing
- Uniform Location of orders
- Quality of Record
- Policy on Verbal Orders
- List of High-risk medication
- Verification of High-risk Medication Orders

Standard 9

Dispensing

- Documented Policies and Procedures
- Medication Recall Procedure
- Monitoring Expiry Dates
- Labelling Requirements

Standard 10

Administration

- Who can administer Medication
- Labeling of Prepared Medication
- Patient Identification
- Verification of Medication
- Verification of Dosage
- Verification of Route
- Verification of Timing
- Documentation of Medication
- Self- Administration
- Medications brought from outside

Core elements of the Functional Area:

1. Documented policies and procedures for prescription, storage, dispensing and administration of medication
2. List and SOPs of High Risk Medication
3. Policy for medication recall
4. Documented labelling requirements

Standard 8. MOM-1:

Policies and procedures exist for the prescription of medications

Intent Statement

This standard requires that there should be policies and procedures for the prescription of medications in the HCEs. The HCEs are therefore, required to maintain documented SOPs which formally determines who can write the prescription / medications orders. The SOPs are also required to determine that the orders are written in a uniform location in the medical records clearly, legibly and are dated, timed, named and signed. Policy on verbal orders, defining and enlisting the high-risk medicines/medications and verification of the orders prior to dispensing/administration are also required to be documented and implemented.

Ind. 51 Documented policies and procedures exist for the prescription of medications

Survey process

Review pharmacy and medication policies that relate to prescribing staff, administering staff and pharmacy staff. The policies should explicitly define that how medication orders/prescriptions must be written, including where in the in-patient record or on an outpatient form, which staff can prescribe and which staff can administer. The policy should also inform what is done when there is confusion about the prescription / order[21].

Compliance Requirements

Documented policies including:

i. How medication prescriptions (manual as well as computerized) must be written
ii. Where the medication orders are written in the in-patient record or on an outpatient form
iii. Which category of staff can prescribe and which category of staff can dispense/administer
iv. What is done when the order or prescription is confusion about the order

Assessment

	Compliance Requirements	Evidence
i.	Documented Policies	Document Review

Scoring

- If there are policies for prescription/ordering of medications and the policy explicitly defines what is done when the prescription or order is not clear, then score as **fully met.**
- If there are policies for prescription/ordering of medication, but the policy does not define what is to be done when the prescription/order is not clear, then score as **partially met.**
- If there are no observable policies, then score as **not met.**

21- Example – contraindicated due to other drugs prescribed or allergy, adult dose for child or restricted; wrong patient name or illegible

Ind. 52 The organization formally determines who can write orders

Survey process

There should be a policy that identifies practitioners who may write medication orders in the medical record or on a prescription. Legally, only medical, dental, tibi and homeopathic practitioners registered with their respective federal councils can write the prescriptions/medication orders. However, determine if any other professionals such as midwives, anaesthetic nurses, emergency nurses, optometrists, podiatrists and psychologists are permitted to write 'limited prescriptions or order medication'. The policy should delineate which practitioners can prescribe restricted classes of drugs[22]

Compliance Requirements

i. Formal notification/office order authorizing the particular professionals regarding prescription/medication orders

ii. Separate formal notification/office order which authorizes the particular professionals regarding prescription/medication orders of restricted classes of drugs

iii. The above Notifications are on a prescribed format for such orders

Assessment

	Compliance Requirements	Evidence
i.	Notification for authorization of professionals	Document Review
ii.	Notification of professionals for prescription of restricted classes of drugs	Document Review
iii.	Format of notification	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met**

Ind. 53 Orders are written in a uniform location in the medical records

Survey Process

Review a sample of at least 10 in patient files for verifying the location of medication orders on the correct/specified place. While reviewing medical records determine whether medication orders are uniformly written in the same location which is specified for writing such orders in the record across various wards in the health care establishment or not.

Compliance Requirements

i. The Medical record containing medication / prescription orders on the correct/specified location

22- Example – chemotherapy or very expensive drugs or unlicensed drugs administered as part of a research programme

Assessment

	Compliance Requirements	Evidence
i.	Medication orders documented on the correct location in the MR	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 54 Medication orders are clear, legible, dated, timed, named and signed

Survey Process

While reviewing medical records, determine if ALL medication orders are legible, dated, timed, named, and signed. A sample of at least 10 in-patient files should be reviewed for ascertaining the clarity in writing. The score is based on the cumulative findings of ALL the records reviewed.

Compliance Requirements

i. Clarity in writing the orders including name of medication, its potency, dose, route, frequency and duration
ii. Legibility of the text of medication orders in terms of hand writing and spelling etc.
iii. Completeness regarding name, signature of the prescriber and the date and time

	Compliance Requirements	Evidence
i.	Clarity of orders	Document Review
ii.	Legible text of medication orders	Document Review
iii.	Completeness of orders	Document Review

Assessment

Scoring

- If the medication orders are legible, dated, timed, named, and signed as above, then score as **fully met.**
- If only 1-2 orders are not timed, then score as **partially met.**
- If 3 or more orders are not legible, dated, timed, named, and signed, then score as **not met.**

Ind. 55 Policy on verbal orders is documented and implemented

Survey Process

Interview nurses and other personnel who receive verbal orders. Observe a staff member receiving a verbal order. The documented policy and practice should clearly describe the process including writing down the verbal order and reading it back to ensure that it was clearly understood by both, the person who gave the order and the person who received the order. Customarily the verbal orders are to be documented in red ink and signed by the receiving staff and to be validated by the ordering physician as soon as possible.

Compliance Requirements

i. Documented SOPs on verbal orders

ii. Evidence of implementation of SOPs on verbal orders
iii. Awareness of relevant staff about verbal orders is evident through interview of randomly picked staff

Assessment

	Compliance Requirements	Evidence	
i.	Documented SOPs	Document Review	
ii.	Evidence of implementation of SOPs	Interview	Document Review
iii.	Awareness of relevant staff about verbal orders is evident through interview of randomly picked staff	Interview	

Scoring

- If there is a clear policy and practice regarding verbal orders, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 56 The organization defines and enlists the high-risk medicines/ medications

Survey Process

Review the definition/description of high risk medicines/medication for the understanding of care providing staff. Check the list of high risk medicines/medication which must be readily available to staff. The list must include at least the concentrated electrolytes such as KCl, chemotherapy drugs, very high cost drugs, look alike medications and sound alike (LASA) medications and the psychotropics etc.

Compliance Requirements

i. Definition/description of high risk medicines/medications for understanding of the staff
ii. List of high risk medicines including the Look Alike and Sound Alike (LASA) drugs readily available to the staff and ideally displayed at nursing station/s and pharmacy

Assessment

	Compliance Requirements	Evidence	
i.	The high risk medicines including the Look Alike and Sound Alike defined and listed	Interview	
ii.	Staff awareness on high risk medicines	Interview	Document Review
iii	List of high risk medicines readily available to the staff and displayed at nursing station/s and pharmacy	Document Review	

Scoring

- If the above requirements are complied, then score as **fully met.**
- If the hospital has defined the list of high-risk medications including the Look Alike and Sound Alike (LASA) drugs and is readily available to the staff and displayed at 80% of nursing stations and pharmacy, then score as **partially met.**
- If there is no list of high-risk medications, then score as **not met.**

Ind. 57 High-risk medication orders are verified prior to dispensing/ administration

Survey Process

Interview both pharmacy and nursing staff as the dispensing and administration of high risk medicines to see that they understand and practice accordingly as it is a significant safety issue.

Compliance Requirements

i. Documented SOPs on verification of high risk medicines prior to dispensing and administration at all nursing stations/pharmacy
ii. Evidence that high risk medicine orders are verified before dispensing
iii. Awareness of relevant staff about SOPs is evident through interview of randomly picked staff

Assessment

	Compliance Requirements	Evidence	
i.	SOPs on verification of high risk medicines	Document Review	
ii.	Evidence that the SOPs are practiced	Interview	Document Review
iii.	Awareness of relevant staff about SOPs is evident through interview of randomly picked staff	Interview	

Scoring

- If there is a clear practice (based on interviews with pharmacy and nursing personnel) of verifying the order for high-risk medications, then score as **fully met.**
- If there is no formally defined process, or if it is not practiced, then score as **not met.**

Standard 9. MOM-2:

Policies and procedures guide the safe storage and dispensing of medicines /medications

Intent Statement

In order to comply with this standard, the HCEs are required to have the policies and procedures to guide the safe storage and dispensing of medicines/medications. The HCEs are required to implement the SOPs for safe storage and dispensing of medicines/medications. The policies should also include implementation of procedure for medication recall, checking the expiry dates, labelling and documentation prior to dispensing/administration.

Ind. 58 There are SOPs to guide on safe storage and dispensing of medicines and these are implemented

Survey Process

The policies should include SOPs for safe storage and matching the order with the correct patient and medication, confirming look alike drugs, and labelling before dispensing of medication etc.

Compliance Requirements

I. Documented SOPs for safe storage of medicines/medications covering aspects of temperature, ventilation, humidity, sunlight and stacking etc.
ii. Documented SOPs for safe dispensing
iii. Evidence that the above SOPs are implemented

Assessment

	Compliance Requirements	Evidence	
i.	Documented policy / SOPs for safe storage and dispensing	Document Review	
ii.	Evidence of implementation of SOPs	Interview	Document Review

Scoring

- If there are policies, procedures with evidence of being implemented, then score as **fully met.**
- If there is inconsistent implementation of above policies, procedures, then score as **partially met.**
- If there are no policies, procedures or if none have been implemented, then score as **not met.**

Ind. 59 The policies include a procedure for medication recall

Survey Process

While visiting the pharmacy, review the procedure for medication recall. Review the documentation of how it was to be done in case of a recall. The HCE should be encouraged to establish pharmacovigilance committees.

Compliance Requirements

i. Documented SOP on the medicines/medication recall procedures are available
ii. Evidence that the procedure was followed on occurrence of such a need or convincing documentation that it would be followed should such a need arise

Assessment

	Compliance Requirements	Evidence	
i.	Documented SOP on recall procedure	Document Review	
ii.	Evidence that SOPs on recall procedure are followed in case of a need	Interview	Document Review

Scoring

- If there is a procedure/ SOPs for medication recall, then score as **fully met.**
- If there is no procedure/SOPs or if it is not complied, then score as **not met.**

Ind. 60 Expiry dates are checked and documented prior to dispensing.

Survey Process

The essence of this indicator is to ensure that expiry dates of each medicine/medication is cheeked before dispensing to the patient units/wards/patients and then before being administered to the patients in the wards/patient units. This is best surveyed by observation. While on a patient unit, check a sample of medicines/ medications for their expiration date. Check the procedure where stock bottles are used to ensure that stock is rotated.

Compliance Requirements

i. Written policy for checking expiry date and near expiry medication
ii. Evidence that the policy for checking expiry date is practiced
iii. Verify that there is no expired drug in the stock in the ward and pharmacy/store

Assessment

	Compliance Requirements	Evidence	
i.	Documented policy for monitoring the expiry date and near expiry medication	Document Review	
ii.	Policy for checking expiry date is practiced		
ii.	Physical Verification that there is no expired drug in the stock/ working shelves	Observation	Document Review

Scoring

- If there is policy to monitor the expiry date and it is complied, and no expired medications are found, then score as **fully met.**
- If there is no policy or if the policy is not complied and/or if there is any expired medication found in the working shelves, then score as **not met.**

Ind. 61 Labelling requirements are documented and implemented by the organization

Survey Process

The hospital should have defined what is to be included on the label or prescription in addition to the packing and labelling requirements defined under the Labelling Rules. When being dispensed directly to the patient this should include at least: 1. Patient's name, 2. Generic and proprietary name of medicine, 3. Concentration (dose), 4. Directions for use, 5. Prescribing practitioner and 6. Date of dispensing. When dispensed to a patient care unit the label should include ALL the above information. Check a sample (10-15) of dispensed medications to determine how they are labelled.[23] This is an important patient safety issue.

Compliance Requirements

i. Documented SOPs for labelling including the requirements for:
   a. All I/V fluids and when the injections are mixed with the I/V fluids, these are labelled prior to dispensing/ administration
   b. Multiple medications for single patient such as in operating room or emergency room
   c. All medications given to outpatients

ii. Labeling requirements
   a. Patient's name
   b. Medicine name
   c. Dose and route
   d. Direction for use
   e. Prescriber's name
   f. Date of dispensing

Assessment

	Compliance Requirements	Evidence	
i.	Documented SOPs for labelling	Document Review	
ii.	Verification of labelling requirements	Interview	Document Review

Scoring

- If the above requirements are complied, and all medications are appropriately labelled, then score as **fully met.**
- If any of the above requirements is not complied/ if even one drug is not completely labelled, then score as **not met.**

23- It is recognized that the establishment of appropriate systems may require a negotiated implementation time frame in some institutions

Standard 10. MOM-3:

There are defined procedures for medication administration

Intent Statement

This standard requires defining the procedures for medication administration. This is achieved by laying down the requirement that the medications are administered by those who are permitted by law to do so. It further requires that the prepared medications are labelled prior to preparation of a second drug, patient is identified prior to administration, medication is verified from the order prior to administration, and the dosage, route, timing is verified from the order prior to administration. Medication administration is followed by documentation in the medication chart/ log. The standard also requires defining policies and procedures to govern patient's self-administration of medications and medications brought from outside the organization.

Ind. 62 Medications are administered by those who are permitted by law to do so

Survey Process

Review a sample of 10 medical records to validate that only those permitted by law and the hospital pharmacy policy have administered medication.

Compliance Requirements

i. Authorization of staff to dispense and administer medicines

ii. Evidence that medicines are administered only by those who are authorized/ permitted by law to do so

Assessment

	Compliance Requirements	Evidence	
I.	Documented policy /Authorization of staff to administer medicines in line with the applicable law	Document Review	
ii.	Evidence by verification of sample record to validate that only those permitted by law administer medication	Interview	Document Review

Scoring

- If the above requirements are complied, and all drugs are administered by authorized staff, then score as **fully met.**
- If the survey team finds an example of medication administered by someone not authorized to do so, then score as **not met.**

Ind. 63 Prepared medications are labelled prior to preparation of a second drug.

Survey Process

Observe a nurse or an anesthetist preparing medication. Verify that each medication is labelled prior to preparing the next one.

Compliance Requirements

i. SOPs to ensure that prepared medication are labelled prior to preparation of second dose
ii. Evidence that each medication is labelled prior to preparing the next one

Assessment

	Compliance Requirements	Evidence	
i	Verification that each medication is labelled prior to preparing the next one	Observation	Document Review

Ind. 64 Patient is identified prior to administration

Survey Process

Review the policy and procedure that should include the requirement for at least 2 separate ways of positively identifying the patient. Then interview a nurse to find out what is done in practice when administering medication and observe how the nurse identifies the patient. Patients should have a form of identification that is reliable with them at all times. [24]

Compliance Requirements

I. Documented SOPs for identification of the patient using at least 2 separate ways of positively identifying the patient, is available.
ii. Identification process as per SOPs is in practice.

Assessment

	Compliance Requirements	Evidence	
i.	Documented policy / SOPs for positively identifying the patient	Document Review	
ii.	Evidence for implementation of the policy/ SOPs	Interview	Observation

Scoring

- If the above requirements are complied, by routinely using 2 identifiers, then score as **fully met.**
- If this practice is not uniformly followed (1 or more examples where there is failure to follow the procedure), then score as **not met.**

Ind. 65 Medication is verified from the order prior to administration

Survey Process

Observe nurses or doctors preparing medication and verify that the medication order was available and the type of medication was checked and compared with the order prior to preparing the medication.

Compliance Requirements

I. Documented SOPs for verification of the medication by checking and comparing with the order prior

24- For ALL patients the system employed must be permanently with the patient and fail-safe.

to preparing and administering the medication
ii. Evidence that the verification process is undertaken before administration to the patient

Assessment

	Compliance Requirements	Evidence	
i	Documented policy/SOPs for verification of the medication from the order/s prior to preparing and administering	Document Review	
ii	Evidence for verification	Interview	Document Review

Scoring

- If the above requirements are complied, and there is clear evidence that the order was checked by name, then score as **fully met.**
- If the above requirements is not complied and if ANY example is seen of medication not being checked against the order, then score as **not met.**

Ind. 66 Dosage is verified from the order prior to administration

Survey Process

Observe nurses or doctors preparing medication and verify that the medication order was readily available and the dose was checked prior to preparing the medication.

Compliance Requirements

i. Documented SOPs for dosage verification from the medication order
ii. Evidence that the dosage verification process is undertaken before administration to the patient

Assessment

	Compliance Requirements	Evidence	
i.	Documented policy/ SOPs for dosage verification	Document Review	
ii.	Evidence of dosage verification	Interview	Document Review

Scoring

- If there is clear evidence that the order was checked for dose, then score as **fully met.**
- If ANY example is seen of medication not being checked against the order, then score as **not met.**

Ind. 67 Route is verified from the order prior to administration

Survey Process

Observe nurses or doctors preparing medication and verify that the medication order was readily available and was checked for route of administration prior to preparing the medication.

Compliance Requirements

i. Documented SOPs for verification of route from the medication order prior to preparing /administration of the medication

ii. Evidence that the route verification process is undertaken before preparing / administration to the patient

Assessment

	Compliance Requirements	Evidence	
i.	Documented policy/ SOPs to verify route of medication	Document Review	
ii.	Evidence that the route is verified prior to administration	**Interview**	Document Review

Scoring

- If the above requirements are complied, and there is clear evidence that the order was checked for route of administration, then score as **fully met.**
- If there is any example of medication not being checked against the order, then score as **not met.**

Ind. 68 Timing is verified from the order prior to administration

Survey Process

Observe nurses or doctors preparing medication and verify that the medication order was readily available and was checked for timing prior to preparing and administration of the medication.

Compliance Requirements

i. Documented SOPs for verification of the timing of administration from the medication order

ii. Evidence that medication timings are verified from order before administration to patient

Assessment

	Compliance Requirements	Evidence	
i.	Documented SOPs for verification of the timing of medication	Document Review	
ii.	Evidence of verification of the timing from the medication order	Interview	Document Review

Scoring

- If the above requirements are complied, and there is clear evidence that the order was checked for timing, then score as **fully met.**
- If there is ANY example that the medication is not being checked against the order, then score as **not met.**

Ind. 69 Medication administered is documented

Survey Process

On the same 10 medical records checked earlier, review the physician order then verify that ALL administered medications are documented in the record.

Compliance Requirements

I. Evidence of documentation of the medication administration in all of the checked records

Assessment

	Compliance Requirements	Evidence
i.	Documentation of the medication administration in all of the checked records	Document Review

Scoring

- If ALL administered medications are documented, then score as **fully met.**
- If only 1-2 (cumulative from findings in ALL 10 records) examples of failure to document administration are observed, then score as **partially met.**
- If more than 3 documentation failures are observed, then score as **not met.**

Ind. 70 Policies and procedures govern patient's self-administration of medications

Survey Process

Review the policy on self-administration. Interview a nurse to see if the policy is understood and speak with a patient to determine if they understand the instructions they have been given.

Compliance Requirements

i. Documented policy/ SOPs on self-administration

ii. Policy is understood by the relevant staff and correctly communicated by the staff to the patients and understood by them accordingly

	Compliance Requirements	Evidence	
i.	Documented policy/ SOPs	Document Review	
ii.	Evidence of correct understanding by the staff and communication to the patients	Interview	Document Review

Scoring

- If there is a policy and it is understood, then score as **fully met.**
- If there is no policy or if nurses are unaware of the policy and procedure, then score as **not met.**

Ind. 71 Policies and procedures govern patient's medications brought from outside the organization

Survey Process

Review the policy and procedure. The purpose of this indicator is to see that ordering, identification, and documentation of medication brought into the hospital by the patient is managed as per SOPs. Usually this requires the pharmacy to verify that the medication is the one which was ordered and is safe. Also, that the hospital retains the medication brought by the patient at his own and is not used during the patient's stay in the hospital and is handed over to patient on discharge.

Compliance Requirements

i. Documented policy /SOPs on medications brought from outside the HCE

ii. Evidence that the SOPs are followed

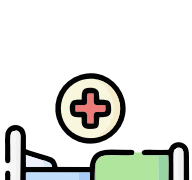
	Compliance Requirements	Evidence	
i.	Documented policy/ SOPs	Document Review	
ii.	Evidence that the SOPs are followed	**Interview**	Document Review

Scoring

- If there is a policy on medication brought from the outside and it is implemented, then score as **fully met.**
- If either there is no policy or it is not implemented, then score as **not met**

Functional Area: Patient Rights and Education

Outline:
Standards: 3 (11-13)
Indicators: 12 (72-83) (**6** + **6**)



Standard 11

General consent and care to the patient

- Information on the scope of General consent
- List of specific situations for informed consent
- Informed consent to be in an understandable language
- Policy for consent if patient is ncapable to give consent

Standard 12

Information on costs

- Uniform Pricing Policy
- Availability of tariff list
- Educating patients on estimated cost of treatment
- Educating patients on financial implications according to changes in treatment settings/ condition

Standard 13

Appeals and complaints

- **Explanation about patient Rights for complaint**
- **Documented and timely management of complaints**
- **Informing patient about progress of complaint**
- **Using result of complaints management for quality improvement process**

Core elements of the Functional Area:

1. General consent requirements.
2. Informed consent requirements and enlisted situations.
3. Policy for pricing and costing of services.
4. Knowledgeable person to communicate the patients about costing.
5. Develop complaints management system for the facilitation of patient rights.
6. System to prioritize the complaints and its investigation, results and outcome in a suitable time frame.

Standard 11. PRE-1:

A documented process for obtaining patient and/or family consent exists for informed decision making about their safe care

Intent Statement

Patients are major contributors to their own safety, and as such, physicians should develop an approach to involve the patients and families in the cycle of decision making at every step of their treatment. Studies show that integrating the patient perspective has the potential to increase the patient's satisfaction. Effective communication with the patients and families also results in better decisions as well as in improved management of the illness and health outcomes.

The HCEs should therefore, define a mechanism whereby patients and families are effectively counselled at every step of their treatment. The HCE shall also define patient and family rights and responsibilities and educate the staff to protect patients' rights. Patients should also be upfront informed of their rights and responsibilities while admitted/ seeking treatment at the time of admission. It is important that they should be informed about the disease, the possible outcomes and should be involved in decision making. The cost implications should also be clearly explained to the patient and/or family. The patients should also be informed about tier right to complaint and educated about the mechanisms available for addressing grievances.

The requirement of this standard is to have a documented process for obtaining patient and/or family consent for informed decision making about their safe care. A General consent for treatment is obtained immediately when the patient enters the organization and seeks medical care. The HCEs are required to enlist those situations where specific informed consent is required considering the human safety. The informed consent includes information on risks, benefits, and alternatives and as to who will perform the requisite procedure. The consent should be taken in a language that the patient and family can understand. The policy should also describe who can give consent when patient is incapable of independent decision-making.

Ind. 72 General consent for treatment is obtained when the patient enters the organization

Survey Process

Review 10 medical records (this can be done simultaneously with review for other reasons). Determine if ALL records document a general consent. Also determine if the contents and the scope of the general consent is made clear to the patient and/or family.

Compliance Requirements

Scope of General Consent form signed by the patient/relative includes at least the following:

i. Information regarding the need for admission
ii. Estimated duration and cost of treatment
iii. Commitment to abide by the rules and regulations of the hospital by the patient
iv. Disclosure of required information regarding illness to the hospital/ physician
v. Seeking permission to share the disease related data with relevant authorities while respecting the patient confidentiality

Assessment

	Compliance Requirements	Evidence
i.	Information regarding the need for admission	Document Review
ii.	Estimated duration and cost of treatment	Document Review
iii.	Undertaking to abide by the rules and regulations of the hospital	Document Review
iv.	Disclosure of required information regarding illness to the hospital	Document Review
v.	Permission to share the disease related data with relevant authorities while respecting the patient confidentiality	Document Review

Scoring

- If ALL records have a documented general consent, then score as **fully met.**
- Since this is a medico-legal issue, if ANY record does not have a general consent, then score **as not met.**

Ind. 73 The organization has listed those situations where specific informed consent is required considering the human safety

Survey Process

Patients are righteous in seeking health care service/s that is/are safe. Review the written policy and list of the situations where specific informed consent is required. Then review 10 medical records of patients which should have (by hospital policy) a specific informed consent to validate that it is included in the record. This would include consent related to procedures and therapies having concerns about human safety, inter-alia, including anesthesia, surgery, sterilization (vasectomy or tubal-ligation), termination of pregnancy and high-risk medications etc.

Compliance Requirements

i. List of situations where informed consent is required

ii. Duly completed informed consents available in all of the patients' records checked where they were necessary

Assessment

	Compliance Requirements	Evidence
i.	List of situations where informed consent is required	Document Review
ii.	Duly completed informed consents available in all the checked records where they were necessary	Document Review

Scoring

- If ALL records document an informed consent, then score as **fully met.**
- Since this is also a medico- legal issue, if ANY records do not document consent, then score as **not met.**

Ind. 74 Informed consent includes information on risks, benefits, and alternatives and as to who will perform the requisite procedure in a language that they can understand

Survey Process

This indicator relates to the "informed" part of informed consent addressing the human safety concerns. Review the same 10 records as for above to verify if the required information is included and documented.

Compliance Requirements

i. All reviewed patients' files contain informed consent exhibiting the evidence that following information about the procedure have been conveyed by the authorized professional to the patient/next of kin as applicable:
   a. Risks
   b. Benefits
   c. Alternatives
   d. Who will perform the procedure
   e. Type of procedure/s

ii. Signature of patient / next of kin (Parents, Siblings, Spouse, Children, Guardian, Attorney or even the Care Provider

iii. Signature of the authorized professional

Assessment

	Compliance Requirements	Evidence	
i.	All reviewed patients' files have informed consent and evidence of information having been conveyed by the authorized professional to the patient/next of kin as applicable, bearing signature of patient / next of kin	Observation	Document Review
ii.	Signature of the authorized professional	Document Review	

Scoring

- If ALL records document informed consent as above, then score as **fully met.**
- Since this is also a medico-legal issue, if ANY records do not document informed consent, then score as **not met.**

Ind. 75 The policy describes who can give consent when patient is incapable of independent decision-making

Survey Process

Review the policy to determine who is identified as being able to give consent in addition to the patient in case when the patient is incapable of doing so due to any reason. Also review the implementation of the policy.

Compliance Requirements

i. Documented policy as to who can give the consent in case when the patient is incapable of doing so himself due to any reason

ii. Evidence of implementation of the policy as applicable

Assessment

	Compliance Requirements	Evidence
i.	Documented policy as to who can give the consent in case when the patient is incapable of doing so	Document Review
ii.	Evidence of implementation of policy	Document Review

Scoring

- If there is a policy describing who, other than the patient, may give informed consent and it is complied, then score as **fully met.**
- If there is no policy or if it is not complied, then score as **not met.**

Standard 12. PRE-2:

Patient and families have a right to information on expected costs

Intent Statement

The standard acknowledges that patient and families have a right to information on expected costs under a uniform pricing policy in a given setting. It also requires the tariff list to be available to patients and family who should be educated about the estimated costs of treatment and also informed about the financial implications when there is a change in the patient condition or treatment setting.

Ind. 76 There is uniform pricing policy in a given setting (out-patient and ward category)

Survey Process

This indicator requires uniformity of pricing of services in a given setting e.g. out-patient and in-patients/wards. Visit the finance or billing office to review the policy and verify that it is uniformly applied.

Compliance Requirements

i. Documented uniform pricing policy covering the following aspects:
   a. Policy is uniformly applied in the given setting
   b. Mode and schedule of payment
   c. Process of information to the patient regarding the estimated cost
   d. Procedure to inform the patient/family about the cost of treatment in a particular setting

Assessment

	Compliance Requirements	Evidence
i.	Documented pricing policy	Document Review

Scoring

- If the policy is uniformly applied, then score as **fully met.**
- If the survey team finds evidence that the policy is uniformly applied, then score as **not met.**

Ind. 77 The tariff list is available to patients

Survey Process

Review the tariff list and then ask how it is made available to the patients. Customarily this is only upon the patient's request. However, frequently the tariff list is posted in the outpatient areas or in the admission office. Patients should be made aware that the tariff list is available.

Compliance Requirements

i. Tariff list made available to patients in any way

Assessment

	Compliance Requirements	Evidence
i.	Tariff list made available to patients	Document Review

Scoring

- If there is evidence that the tariff list is readily available to patients, then score as **fully met.**
- If there is no procedure to make it available to patients, then score as **not met.**

Ind. 78 Patients and family are educated about the estimated costs of treatment

Survey Process

Review the process used to inform/educate the patient and/or family about the estimated costs. Also determine if this is done by someone who is knowledgeable of the related details (someone authorized from accounts section or in charge ward or in charge doctor).

Compliance Requirements

i. Designated suitable staff member to educate the patient/family about the cost of treatment
ii. Evidence that the patient / family members are educated about the estimated cost by the concerned staff

Assessment

	Compliance Requirements	Evidence	
i.	Designation of a suitable staff member to educate the patient/family about the cost of treatment	Observation	Document Review
ii.	Evidence that the patients are educated about the estimated cost by the concerned staff	Interview	Document Review

Scoring

- If there is a process to inform patients and/or families about the estimated costs and it is done by an authorized person, then score as **fully met.**
- If there is a process to inform patients and/or families about the estimated costs but it is not done by the authorized person, then score as **partially met.**
- If there is no process, then score as **not met.**

Ind. 79 Patients and family are informed about the financial implications when there is a change in the patient condition or treatment setting

Survey Process

Review the process to determine what prompts the patient and/or family to be informed, including who makes the decision and who provides the information. Typically, a change in patient's condition would prompt shifting to and back from ICU or CCU causing the change in the cost of treatment.

Compliance Requirements

i. SOPs about informing the patient/ family on financial implication when there is change in the patient condition or treatment setting
ii. Designated suitable staff member to educate the patient/family about the change in cost of treatment
iii. Evidence that the patient / family members are educated about the financial implications by the concerned staff

Assessment

	Compliance Requirements	Evidence	
i.	Designated suitable staff member to educate the patient/family about the change in cost of treatment	Observation	Document Review
ii.	Evidence that the patient / family members are educated about the financial implications by the concerned staff	Observation	Document Review

Scoring

- If there is a consistent process, including when it is done, who makes the decision, and who provides the information, then score as **fully met.**
- If there is a process, but there are no clear guidelines of when it is done or who provides the information, then score as **partially met.**
- If there is no process, then score as **not met.**

Standard 13. PRE-3:

Patient Rights for Appeals and Complaints

Intent Statement

The standard calls for patient rights for appeals and complaints if they so choose due to their not being satisfied with the services provided by the HCE. While extending such rights, it requires that the organization informs the patient of his/her right to express his/her concern or complain either verbally or in writing. There should be a documented process for collecting, prioritizing, reporting and investigating complaints in a fair and timely manner. The organization should inform the patient of the progress of the investigation at regular intervals and also about the outcome of investigation. It is also required that the organization uses the results of complaints investigations as part of the quality improvement process.

Ind. 80 The organization informs the patient of his/her right to express his/her concern or complain either verbally or in writing

Survey Process

Determine how the HCE informs the patients and their relatives about their rights to express concern or lodge a complaint about the services being provided, verbally or in writing. This can be verified by interviewing the patients / attendants.

Compliance Requirements

i. HCE informs the patients and their relatives by prominently displaying in the local language, their rights to express concern or lodge a complaint about the provided services

ii. Providing guidance on how to submit a complaint at the places such as reception desk, waiting area, OPDs, main entrance etc.

Assessment

	Compliance Requirements	Evidence
i.	HCE informs the patients and their relatives by prominently displaying in the local language, their rights to express concern or lodge a complaint about the services provided	Document Review
ii.	Providing guidance on how to lodge a complaint at the places such as reception desk, waiting area, OPDs, main entrance etc.	Document Review

Scoring

- If there are policies to inform the patients about their right to complain and handling of appeals and the files substantiate that the patients are informed and the appeals are handled according to the policies, and there is prominent display of the complaint lodging mechanism through standees, LCD (preferable) and other means at all prominent places such as reception, waiting areas, OPD, IPD then score as **fully met.**
- If there are policies to inform the patients about their right to complain and handling of appeals and the files substantiate that the patients are informed and the appeals are handled according to the policies, and there is prominent display of the complaint lodging mechanism through standees, LCD (preferable) and other means, but not at all prominent places such as reception, waiting areas, OPD, IPD, then score as **partially met.**
- If there is no policies to process the complaints, then score as **not met.**

Ind. 81 The organization informs the patient of his/her right to express his/her concern or complain either verbally or in writing

Survey Process

Determine how the HCE informs the patients and their relatives about their rights to express concern or lodge a complaint about the services being provided, verbally or in writing. This can be verified by interviewing the patients / attendants.

Compliance Requirements

i. Documented process / SOPs regarding complaint management system including the following:
a. Collection / receiving of complaints
b. Prioritization
c. Reporting
d. Investigating
e. Resolving
ii. Evidence that the SOPs are implemented

Assessment

	Compliance Requirements	Evidence
i.	Documented process/ SOPs regarding the complaint management system	Document Review
ii.	Evidence that the SOPs are implemented	Document Review

Scoring

- If there are policies containing processes and SOPs for collecting, prioritizing, reporting, and investigating complaints and evidence that these are implemented, then score as **fully met.**
- If there are policies for collecting, prioritizing reporting and investigating complaints but no complaint was registered in last quarter, then score as **partially met.**
- If there are no policies for collecting, prioritizing, reporting and investigating complaints, then score as **not met.**

Ind. 82 The organization informs the patient of the progress of the investigation at regular intervals and inform about the outcome

Survey Process

Review the complaint management/ redressal files to see that the process undertaken includes all the elements associated with managing a complaint as described in the preceding indicator and provides evidence of progressive follow-up with complainants.

Compliance Requirements

i. Informing the patient about the progress at regular intervals and the outcome of the complaint
ii. Evidence on record to establish that the complainant has been informed of the progress minimum at the following three stages:

a. Confirmation of the receipt /maintainability of complaint, issuance of a tracking number along with the name of the contact person at the HCE and the further course of action. This should be done within a prescribed time preferably not exceeding 24 hours.

b. Completing the investigation process and conveying the outcome preferably within 5 - 7 working days OR stating that the matter is being investigated and would require more time (an estimated time to be stated) to complete the process.

c. Conveying the outcome with in a prescribed time frame and informing about right to appeal against the decision within 15 days.

Assessment

	Compliance Requirements	Evidence		
i.	Confirmation of the receipt /maintainability of complaint, issuance of a tracking number and the name of contact person at the HCE and further course of action	Observation	Document Review	
ii.	Completing the redressal process and conveying the outcome within prescribed time frame (preferably 5-7 working days) or informing that the matter would require some more time	Observation	Document Review	
iii.	Conveying the outcome	Observation	Interview	Document Review

Scoring

- If there are policies to inform the patients about the progress and the outcome of the investigation, and the policies are implemented, then score as **fully met.**
- If there are policies to inform the patients about the progress and the outcome of the investigation, but no complaint was registered in last quarter and complaints record is maintained and being nil reported on monthly basis, then score as **partially met.**
- If there are no policies to inform the patients about the progress and outcome of the investigation, then score as **not met.**

Ind. 83 The organization uses the results of complaints investigations as part of the quality improvement process

Survey Process

Review the process and documentation. Identify and observe the actual examples of policy and procedure changes that have been made as a result of complaints analysis for improving the system.

Compliance Requirements

i. Documented actions for improvement of processes on the basis of investigations

ii. Evidence of implementation of the orders leading to improvement

Assessment

	Compliance Requirements	Evidence
i.	Documented actions for improvement	Document Review
ii.	Evidence regarding of implementation of the orders	Document Review

Scoring

- If there is a quality improvement process to use complaint handling data and reports are available, then score as **fully met.**
- If there is a quality improvement process to use complaint handling data and no evidence available how that data was used for improvement, then score as **partially met.**
- If no quality improvement process about using complaint – handling data, then score as **not met.**

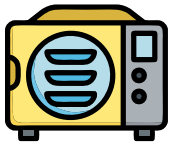
Functional Area: Infection Prevention & Control

Outline:
Standards: 2 (14-15)
Indicators: 9 (84-92) (**3** + **6**)

Standard 14

IPC (IPC) Programme

- Documented IPC Programme
- IPC Committee
- IPC Team
- IPC Nurse
- System/Eqipment for PC
- Handling of Medical Wastes



Standard 15

Sterilization Activities

- Space for sterilization
- Validation Tests
- Recall Proecedures

Core Elements of the Functional Area:
1. Documented IPC Plan (Policies and Procedures)
2. Composition of IPC Committee and defined TORs
3. Composition of IPC Team and defined roles and responsibilities
4. Designated IPC Nurse/ Officer
5. Hospital Waste Management Plan
6. Layout and staffing of sterilization department /CSSD
7. Record of sterilization Validation Tests
8. Recall procedure

Standard 14.

IPC-1: The organization has a well-designed, comprehensive and coordinated infection prevention and control programme aimed at reducing/eliminating risks of Healthcare associated infections to patients, visitors and providers of care

Intent Statement

The standard reminds the HCEs about the need to have a well-designed, comprehensive and coordinated infection prevention and control programme. This should be aimed at reducing/eliminating risks of Healthcare Associated Infections (HAIs) to patients, visitors and providers of care. It requires the HCE to notify a multi-disciplinary Infection Prevention and Control Committee, also known as environmental safety committee with well-defined roles as a unit and for individual members.

The hospital has an infection prevention and control team, a designated qualified infection control nurse(s) for this activity. The establishment is required to have plan and provisions in terms of consumables and equipment for hospital waste management from the point of generation to the point of destruction. All staff involved in the creation, handling and disposal of medical waste shall receive regular training and ongoing education in the safe handling of medical waste.

Ind. 84 The hospital infection prevention and control plan is documented which aims at preventing and reducing risk of Healthcare associated infections

Survey Process

There should be a written hospital infection prevention and control plan. The surveyors will assess that the plan covers at least; the Surveillance activities, Hand hygiene procedures, Isolation procedures, and the responsibilities and authorities of the Infection Prevention and Control Committee.

Compliance Requirements

i. Documented Infection Prevention & Control Programme covering the following essential components:

- a. Hand Hygiene
- b. Respiratory Hygiene
- c. Use of PPE
- d. Needle stick/Sharps Safety
- e. Safe Injection Practices
- f. Immunization of the staff
- g. Emergency Action Plan
- h. Environmental Health and Food Safety
- i. Sterilization and Surface Disinfection
- j. Waste Management

ii. Surveillance Activities (Active and Passive)

- a Healthcare-associated infections (HAI) (outcomes)
- b. Patient care practices aimed at preventing HAI (processes)

iii. Roles and Responsibilities of the Infection Prevention and Control Committee

Assessment

	Compliance Requirements	Evidence		
i.	**IPC Plan covering essential components**			
	a. Hand Hygiene	Observation		
	b. Respiratory Hygiene	Observation	Interview	
	c. PPE	Observation	Interview	
	d. Needle stick/Sharps Safety	Interview	Document Review	
	e. Safe Injection Practice	Observation	Interview	
	f. Hazards Communication	Interview	Document Review	
	g. Immunizations and use of PEP	Document Review		
	h. Environmental Health & Food Safety	Observation	Interview	Document Review
	i. Sterilization and Surface Disinfection	Observation	Interview	Document Review
	j. Waste Management	Observation	Interview	Document Review
ii.	Surveillance	Document Review		
iii.	Roles and Responsibilities of the Infection Prevention and Control Committee	Document Review		

Scoring

- If there is a documented infection prevention and control plan that includes at least surveillance activities, hand hygiene procedures, isolation procedures, and the responsibilities and authorities of an Infection Control Committee, then score as **fully met.**
- If there is a documented plan but it does not define the authority of the IPC committee, then score as **partially met.**
- If there is either no written plan, or it does not include at least 3 of the 4 requirements above, then score as **not met.**

Ind. 85 The hospital has a multi-disciplinary Infection Prevention and Control Committee/ Environmental Safety Committee

Survey Process

Review the constitution of multidisciplinary infection prevention and control/environmental safety committee for appropriateness and the minutes of the meeting of the committee for their attendance, observations and the recommended actions. The membership should have representation of all the

Departments and specialties including senior managers, doctors and nurses as a minimum. It is important for HoDs to ensure their own attendance; however, they may depute some knowledgeable person from their Department/specialty in case of other unavoidable commitment. The surveyors will assess all the compliance requirements of this indicator individually while inquiring for all 3 types of evidence.

Compliance Requirements

i. Constitution of the IPC Committee notified as per the National IPC Guidelines with representation from all relevant departments
ii. TORs of Committee defining roles, responsibilities and authorities
iii. Documented minutes of the IPC Committee meetings covering observations and the recommended actions

Assessment

	Compliance Requirements	Evidence
i.	Notified IPC Committee	Document Review
ii.	Representation from relevant departments in the Committee	Document Review
iii.	TORs of Committee	Document Review
iv.	Minutes of the IPC Committee meetings	Document Review

Scoring

- If all the above 4 compliance requirements are complied, then score as **fully met.**
- If all the above 4 compliance requirements are complied, then score as **not met.**

Ind. 86 The hospital infection prevention and control plan is documented which aims at preventing and reducing risk of Healthcare associated infections

Survey Process

Customarily the team consists of a doctor, a nurse, a laboratory scientist/technician, someone from housekeeping, and a safety officer. The appropriateness of membership of an infection prevention and control team will vary from hospital to hospital according to the needs to manage the workload. The role of the team is to respond to, and communicate the observations of the Infection Prevention and Control Committee to the care providers and make periodic infection control rounds in the hospital to verify that infection control policies and procedures are effectively followed and documented. The surveyors will therefore, assess all the compliance requirements of this indicator individually while inquiring evidence in respect thereof.

Compliance Requirements

I. Notified IPC Team with members (having at least one doctor and one nurse) /composition as per National IPC Guidelines
ii. Roles and responsibilities of the IPC Team
iii. Record of tasks accomplished by the Team as per observations and recommendations of the Infection Prevention and Control Committee
iv. Evidence of making periodic infection control rounds

Assessment

	Compliance Requirements	Evidence
i.	IPC Team notification and constitution	Document Review
ii.	Roles and responsibilities of Team	Document Review
iii.	Record of tasks accomplished	Document Review
iv.	Evidence of making periodic infection control rounds	Document Review

Scoring

- If all the above 4 requirements are complied, then score as **fully met.**
- If the Infection Prevention and Control Committee has not made any observations and recommendations for IPC team, then score as **partially met.**
- If any two of the of the above 4 requirements are not met, then score as **not met.**

Ind. 87 The hospital has designated qualified infection control nurse(s) for this activity

Survey Process

Review the job description of the infection control nurse (ICN) or nurses and also determine the required qualifications. The surveyors will assess all the compliance requirements of this indicator while reviewing the human resource file for this individual(s) to validate if their qualifications match the requirements of the job description.

Compliance Requirements

i. Qualified Nurse with training in IPC designated accordingly (preferably one per 250 beds)
ii. The qualification matches the JD detailed in human resource file

Assessment

	Compliance Requirements	Evidence
i.	Designated qualified IPC Nurse	Document Review
ii.	Detailed Job Description and qualification of the IPC Nurse	Document Review

Scoring

- If qualifications of the individual(s) match the requirements in the job description, or if there are only minor variances (such as a little less experience than noted in the job description, then score as **fully met.**
- If the job description and qualifications of the infection control personnel do not match, then score **not met.**

Ind. 88 The establishment has appropriate consumables, collection and handling systems, equipment and facilities to manage the control of infection

Survey Process

The hospital should have a documented hospital waste management plan including; adequate cleaning equipment, readily available appropriate consumables and the staff trained to use the cleaning equipment and the consumables to effectively manage the infection control and the hospital waste from the point of generation to the ultimate disposal.

Observe the clinical areas and check for the presence and use of; i. Hand washing facilities (water supply and soap/liquid) in ALL care and treatment areas, ii. Gloves, iii. Masks, iv. Sharps collection containers, v. Single use syringes and vi. A full system of waste management from the point of generation to the point of destruction. Adequate systems and facilities with safety /cleaning equipment (PPE etc.), consumables and training of the staff for effective use of the equipment and consumables should be observable. The surveyors will assess all the compliance requirements of this indicator while inquiring availability and evidence regarding use of the same.

Compliance Requirements

i. Documented hospital waste management (HWM) plan

ii. Notification and composition of the HWM Team in line with the provisions of the PHWM rules 2014 and the Hepatitis Control Act 2019

iii. **HWM** facilities/arrangements for:

- a. Segregation
- b. Collection
- c. Transportation
- d. Storage
- e. Disposal/ Minimization
- f. Documentation

Assessment

	Compliance Requirements	Evidence	
i.	HWM Plan	Document Review	
ii.	HWM Team	Document Review	
iii.	Facilities to manage IPC and HWM	Interview	Document Review

Scoring

- If all the above 3 requirements for hospital waste management from the point of generation to the final disposal, including; fully resourced hand-washing and sharps disposal facilities to service all care and treatment areas, and trained cleaning staff with appropriate facilities are complied, then score as **fully met.**
- If there are fully resourced facilities, cleaning staff and facilities in most of the areas and only missing in areas like OPD, then score as **partially met.**
- If any one of the above requirements is not complied in major clinical areas or if there is no HWM plan, then score as **not met.**

Ind. 89 All staff involved in the creation, handling and disposal of medical waste shall receive regular training and ongoing education in the safe handling of the medical waste

Survey Process

Identify the staff who conducts training in infection control and disposal of medical waste and review the training manual. Speak with a range of staff involved with the generation, handling and management of medical waste to determine their level of training and applied knowledge. This should include the temporary or short-term staff as well. The training should encompass the full process on site and include what happens once the waste leaves the site for the sake of knowledge and decision making regarding MOU with the contractor. Adequate systems, facilities, safety equipment/consumables and training should be observable. The surveyors will assess the compliance of this indicator while inquiring for the evidence of all the requirements.

Compliance Requirements

I. Training manual has training modules on Infection Prevention and Control and the HWM for training the staff at induction, as refresher and on induction of new equipment

ii. Evidence that training have been conducted at induction, when new waste management systems were introduced or when new consumables or equipment related to medical waste management were employed

iii. Documentary evidence of periodic refresher trainings of the staff involved in patient care regarding the generation, handling and management of hospital waste and on new advancements in infection control

iv. Awareness of the staff on Infection Prevention and Control and the HWM plan

Assessment

	Compliance Requirements	Evidence	
i.	Training manual having modules on Infection Prevention and Control and the HWM	Document Review	
ii.	Training of staff at induction	Document Review	
iii.	Periodic refresher trainings	Document Review	
iv.	Awareness of the staff	Interview	Observation

Scoring

- If there is evidence that training takes place at induction, when new waste management systems are introduced, or when new consumables or equipment are employed related to medical waste and all randomly picked staff is aware of IPC and HWM practices, then score as **fully met.**
- If 80% of the randomly picked staff is aware of IPC and HWM practices, then score as **partially met.**
- IIf no training takes place or if all staff involved in Infection Prevention and Control and the HWM is not trained, then score as **not met.**

Standard 15.

IPC-2: There are documented procedures for sterilization activities in the organization

Intent Statement
The standard requires the organization to have documented procedures and activities for sterilization. It requires availability of adequate space for sterilization activities, regular validation tests for sterilization, record of sterilization and issuance of equipment, instruments, linen etc. The standard also requires existence of system for monitoring sterilization and an established recall procedure which becomes active if breakdown in the sterilization system is identified.

Ind. 90 There is adequate space available for sterilization activities

Survey Process
The surveyors are required to assess this indicator with utmost care considering the risk of cross infection for the humans. The definition of "adequate" includes enough space which accommodates the equipment as per OEM recommendations, the workload is handled with ease and is separated by corridor/passage or at the least by physical barriers like concrete / non-pervious wall to ensure effective separation of 'clean' and 'dirty'. It is important to understand that the concept of separation also includes no crisscross movement of any person even on-duty staff from clean to dirty and from dirty to clean areas to avoid contamination of clean areas and sterilized supplies through apparently clean agents. These areas should also have separate ventilation/heating/cooling systems. The surveyors will assess fulfillment all the requirements of this indicator while inquiring about the evidence of compliance.

Compliance Requirements

I. Proper designing of the area for sterilization activities / layout of CSSD (as applicable)
- a. Adequate Space (depending on the load of activities)
- b. Physical separation of dirty and clean areas
- c. Clean area for storage for sterilized instruments is available
- d. Dedicated person for supervising the sterilization activities is notified

Assessment

	Compliance Requirements	Evidence
i.	Designing and layout of area for sterilization activities /CSSD (as applicable)	
	a. Adequate Space (depending on the load of activities)	Observation
	b. Physical separation of dirty and clean areas	Observation
	b. Clean area for storage for sterilized instruments is available	Observation
	c. Dedicated person for supervising the sterilization activities is notified	Document Review

Scoring

- If there is adequate space including clear separation with adequate barriers, then score as **fully met.**
- If there is inadequate separation, then score as **partially met.**
- If there is no separation, then score as as **not met.**

Ind. 91 Regular validation tests for sterilization are carried out and documented

Survey Process

This is an important patient safety issue. Review the process/procedure to validate that complete sterilization has occurred. This should be uniformly done on each "batch" that is sterilized. There are several methods that can be used (mechanical, chemical or biological/ such as colour change strips etc.). Whatever method is used, it must be effective and documented. The surveyors will observe that the date of sterilization and expiry are clearly indicated on the packaging.

Compliance Requirements

I. Documented procedure to verify that complete sterilization has been occurred. (listed types of validation tests used)

ii. Validation of sterilization is employed for All "batches" that are sterilized by using listed type of test /color change strips

iii. Marking date of sterilization and expiry (as per the packing material used) on each sterilized item /batch

Assessment

	Compliance Requirements	Evidence
i.	Procedure for validation of sterilization	Document Review
ii.	Record of validation of sterilization of all batches	Document Review
iii.	Labelling sterilization and expiry date	Document Review

Scoring

- If there is a process/procedure to verify that complete sterilization has occurred, it is used for ALL "batches" that are sterilized, and it is documented, and production and expiry dates are indicated, then score as **fully met.**
- If there is marking date of sterilization and expiry (as per the packing material used) on sterilized items /batch is deficient only in up to 20% sets, then score as **partially met.**
- If there is no procedure, or if it is rarely (once a day) used, or if it is not documented, or dates are not indicated, then score as **not met.**

Ind. 92 There is an established recall procedure when breakdown in the sterilization system is identified

Survey Process

Review any written recall procedure to be implemented when breakdown in the sterilization systems is identified. Review how the recall was implemented if an actual breakdown had occurred. Check to see if staff members receive training and are aware of the procedure.

Compliance Requirements

i. Documented recall procedure

ii. Evidence of recall procedure implemented and the protocol used to retrieve items sterilized previously when actual breakdown occurred

iii. Staff members receive training and are aware of the procedure

Assessment

	Compliance Requirements	Evidence	
i.	Recall procedure	Document Review	
ii.	Previous record /evidence of recall when breakdown occurred	Document Review	
	Staff training and awareness	Document Review	Interview

Scoring

- If there is a written recall procedure and the staff members are aware of the same and evidence of recall when breakdown occurred, then score as **fully met.**
- If there is no written procedure or if the same is not implemented, or if the staff is not aware of it then score as **not met.**

Functional Area: Continuous Quality Improvement

Outline: Standards: 3 (16-18)
Indicators: 15 (93-107) (**11** + **4**)

Standard 16

Quality Improvement Programme

- Documentation of QI Programme
- Multi- Disciplinary Committee
- Communication and Co-ordination
- Designated Individual for co-ordination
- Composition of QI Programme
- Communication and Co-ordination
- Updating of QI Programme

Standard 17

Key Indicators

- Monitoring Appropriate Patient Assessment
- Quality Control Programme for Diagnostic Services
- Quality Control Programme for Diagnostic Services
- Monitoring Invasive Procedures
- Monitoring Adverse Drug Events
- Monitoring Use of Anestehsia
- Monitoring Use of Blood & Blood Products
- Monitoring Content of Medical Records

Standard 18

Sentinel Events

- Defined Sentinel Events
- Intensive Analysis of Sentinel Events

Core Elements of the Functional Area:

1. Continuous Quality Improvement Programme
2. CQI Committee
3. CQI Coordinator
4. Coordination and Communication of CQI Programme
5. Identification of Key indicators used as tool for continual improvement
6. Identification of Sentinel Events
7. Analysis of Sentinel Events

Standard 16.

CQI-1: There is a structured quality improvement and continuous monitoring programme in the organization

Intent Statement

This standard requires the HCEs to develop and implement a structured quality improvement programme through continuously monitoring the entire spectrum of service delivery. Notification of a Multidisciplinary CQI Committee with well-defined TORs as well as roles of the individual members underpins the entire quality improvement and continuously monitoring activity.

The CQI Committee is supposed to develop and document a comprehensive quality improvement plan. A designated individual, the CQI coordinator is responsible for coordinating and implementing the quality improvement actions on the basis of an overall CQI programme that should comprehensively cover ALL the major elements related to quality assurance and continuous improvement for human safety and risk management. The CQI programme is a continuous process developed in coordination with all concerned and communicated amongst all the employees of the organization through a proper training mechanism for its effectiveness. The CQI progarmme needs to be reviewed and updated at least once in a year.

Ind. 93 The quality improvement programme is developed, implemented and maintained by a multi-disciplinary committee

Survey Process

There should be a written CQI plan that should include at least; i. A multi- disciplinary committee with terms of reference, ii. The CQI methodology to be used, iii. Reporting structure of CQI results, iv. The requirement for minutes of the committee meetings, and v. The responsibilities and authorities of the committee. There should be evidence to demonstrate that there is a process in place to communicate the same amongst the staff that it is regularly updated at least once in a year and a process of staff induction to the programme is in place. Check the written CQI programme that should include at least all the key compliance requirements.

Compliance Requirements

i. A documented Continuous Quality Improvement Programme that includes at least:

a. A multi- disciplinary committee with TORs
b. The methodology to be used for CQI
c. Reporting structure of CQI results
d. The requirement for minutes of Committee meetings
e. The responsibilities and authorities of the CQI committee and individual committee members

Assessment

	Compliance Requirements	Evidence
i.	Documented CQI Programme	Document Review
ii.	Multi- Disciplinary CQI Committee	Document Review
iii.	CQI Methodology	Document Review

iv.	The TORs of CQI Committee	Document Review
v.	Minutes of Committee meetings and Reporting Structure of CQI results	Document Review

Scoring

- If there is a written CQI plan and it includes at least the above 5 requirements (a to e), then score as **fully met.**
- If there is a plan but it lacks defining the responsibilities and authorities of the committee, then score as **partially met.**
- If there is no plan or it includes 3 or fewer of the requirements above, then score as **not met.**

Ind. 94 The quality improvement plan is documented

Survey Process

The minutes of the CQI committee meeting/s held under the quality improvement plan document the issues, activities and outcomes of the meeting. Staff is aware of the document and familiar with the contents.

Compliance Requirements

i. Minutes of the CQI Committee meeting including:
   a. The issues
   b. CQI activities
   c. Outcomes of the meeting

ii. Awareness of the staff about the documented plan and its contents

iii. Documented CQI plan is accessible to staff

Assessment

	Compliance Requirements	Evidence	
i.	Minutes of meeting of CQI Committee Meeting	Document Review	
Ii.	Staff is aware and familiar with the contents of the plan	Document Review	Interview
iii.	Documented CQI plan is accessible to staff	Document Review	Interview

Scoring

- If the quality improvement plan is documented and minutes of CQI Committee meeting highlight the issues, CQI activities and outcomes, then score as **fully met.**
- If the quality improvement plan is documented but the minutes of CQI Meeting do not highlight CQI activities and outcomes, then score as **partially met.**
- If the quality improvement plan is not documented or if the minutes of CQI Committee meeting are not documented or they do not contain any information about the CQI activities then score as **not met.**

Ind. 95 There is a designated individual for coordinating and implementing the quality improvement programme

Survey Process

Customarily there is a designated "Quality Improvement Coordinator" that may either, be a nurse or a doctor or any other health professional. This may be a full time or a part time position assigning additional duties to some health professional depending on the size of the hospital and its scope of services. The person however, should have adequate knowledge and authority to undertake the role and hospital staff members should be aware of the role assigned to the person. There should be a job description that also defines the requisite qualifications and duties assigned to this individual that underpin the human safety requirements.

Compliance Requirements

i. Notification of Quality Improvement Coordinator/Officer
ii. JD of the Quality Improvement Coordinator/Officer defines the requisite qualifications and assigned duties
iii. Awareness of the CQI Coordinator about the CQI activities
iv. Awareness of the staff members about the role assigned to the CQI Coordinator

Assessment

	Compliance Requirements	Evidence
i.	Notification of CQI Coordinator	Document Review
ii.	JD of CQI Coordinator	Document Review
iii.	Awareness of the CQI Coordinator about the CQI activities	Interview
iv.	Awareness of the staff about the role of the CQI Coordinator	Interview

Scoring

- If there is a designated quality improvement coordinator and a defined job description for the individual, then score as **fully met.**
- If there is designated CQI Coordinator and more than 80% staff members are aware about the CQI activities and assigned duties, verified through interview, then score as **partially met.**
- If there is no designated CQI coordinator, then score as **not met.**

Ind. 96 The quality improvement programme is comprehensive and covers ALL the major elements related to quality improvement and risk management

Survey Process

The surveyors are required to be knowledgeable about the definition of "comprehensive" and "ALL major elements" that include at least; i. All departments participate, and ii. All high-risk areas (blood bank, laboratory, operating theaters, emergency room, and equivalent) are covered and iii. Documented all quality improvement activities. This requires some surveyor judgment.

Compliance Requirements

i. All departments participate in the Quality improvement programme activities
ii. All high-risk areas including blood bank, laboratory, operating theatres, emergency room, and equivalent are included in the QI/QA programme
iii. All quality improvement activities are documented

Assessment

	Compliance Requirements	Evidence
i.	Participation of all departments	Document Review
ii.	All high-risk areas included in QI/QA programme	Document Review
iii.	Documented QI activities	Document Review

Scoring

- If all the above requirements are complied, then score as **fully met.**
- If any one of the above requirements is not complied, then score as **not met.**

Ind. 97 The designated programme is communicated and coordinated amongst ALL the employees of the organization through a proper training mechanism

Survey Process

There should be documented evidence that ALL the appropriate staff including a minimum of; i. All the senior leaders, ii. All department heads, and iii. All members of the CQI committee, have participated in a formal training process to ensure that they fully understand the programme. Interview the staff and ask to show examples of the impact of the CQI programme.

Compliance Requirements

I. Documentation as evidence of communication of the CQI programme to all senior leaders, department heads and members of the CQI committee
ii. Formal training process to make all the employees fully understand CQI programme
iii. Coordination amongst all functionaries
iv. Staff understand and show examples of the impact of the CQI programme

Assessment

	Compliance Requirements	Evidence	
i.	Documented communication	Document Review	
ii.	Training process for all key employees / functionaries	Document Review	
iii.	Awareness of the staff about CQI Programme	Interview	Document Review
iv.	Examples of impact of the CQI programme	Observation	

Scoring

- If the above requirements are complied, then score as **fully met.**
- If only 1-2 department heads have not been trained, then score as **partially met.**
- If there has been no training, or it has not included at least the senior leadership, the committee members and "most" of the department heads, then score as **not met.**

Ind. 98 The quality improvement programme is a continuous process and updated at least once in a year

Survey Process

Review the documented evidence that the programme has been reviewed at least once in the past year or at the frequency defined in the hospital's policy.

Compliance Requirements

i. Evidence of the review of CQI programme by the CQI Committee at least once in a year

ii. Evidence that improvements are made as a continuous process as the opportunity arises

Assessment

	Compliance Requirements	Evidence
i.	Evidence of review of CQI Programme	Document Review
ii.	Evidence of improvements made	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Standard 17.

CQI-2: The organization identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tools for continual improvement

Intent Statement
The standard requires the HCEs to identify the key indicators for monitoring the quality of care that include the clinical structures, processes and outcomes. The results of monitoring the indicators are used as tools for the continual improvement in the processes of service provision leading to improvement in the quality of healthcare and treatment outcomes.

The key indicators may inter-alia, include monitoring of appropriate patient assessment, safety and quality control in the diagnostic services, all invasive procedures, adverse drug events, use of anaesthesia, use of blood and blood products and availability and content of medical records etc.

Ind. 99 Monitoring includes appropriate patient assessment

Survey Process
Review the documentation in the CQI committee minutes and while surveying the hospital, ask to see examples of the impact of CQI programme. The impact is reflected in the form of improvement in the quality of care where it was weak in the past and/or elimination/reduction in the untoward incidents where human safety was compromised or was at risk. Examples should be observable at; i. Admission, ii. Regularly through the course of treatment pathway and iii. Based on the condition of the patient, and iv. Documented in the medical record.
In the initial stages healthcare establishments can set and document their own benchmarks. These will eventually be compared across similar institutions and shared with the intent of achieving the right benchmarks across the province.

Compliance Requirements

I. Monitoring the appropriate patient assessment by the CQI committee using at least the following KPIs:
- a. Percentage of outdoor and emergency patients attended for initial assessment within the prescribed time line
- b. Percentage of the inpatient cases where care plan with desired outcome is documented and countersigned by the clinician within the prescribed time line
- c. Percentage of the inpatient cases where screening for nutrition need has been done
- d. Percentage of the inpatient cases where the nursing care plan is documented

Assessment

	Compliance Requirements	Evidence
i.	Monitoring of appropriate patient assessment processes	Document Review
a.	Assessment of outdoor and emergency patients within defined time	Document Review

b.	Inpatient cases with documented care plan with desired outcome countersigned by the clinician	Document Review
c.	Nutritional assessment in indoor patients as needed	Document Review
d.	Cases with documented nursing care plan	Document Review

Scoring

- If there is documented evidence that this has been monitored and examples can be seen in the CQI programme, then score as **fully met.**
- If any of the above requirement is not complied, then score as **not met.**

Ind. 100 Monitoring includes safety and quality control programmes of the diagnostic services

Survey Process

Review the documentation in the committee minutes and check the diagnostic services to observe; i. Documented Standard Operating Procedures (SOPs), ii. Documented SOPs and Occupational Health and Safety (OH&S) protocols, iii. Reference testing to ensure validity, iv. External audit of facilities, procedures and protocols, v. Documented training of staff in SOPs and Occupational Health and Safety (OH&S), and vi. Record of the incidents which did or could have compromised the human safety.

Compliance Requirements

I. Documented SOPs for monitoring safety and quality control programmes of the diagnostic services

ii. Documented SOPs and Occupational Health and Safety (OH&S) protocols

iii. Evidence of monitoring of the following and their presentation in CQI committee meeting:
- a. Percentage of reporting errors out of the total tests for the period under review
- b. Percentage of the re-dos out of the total tests for the period under review
- c. Percentage of the reports correlating with clinical diagnosis out of all histopathology tests in case of lab and all CT and MRI in case of radiology

iv. Evidence that staff are properly trained on Occupational Health and Safety (OH&S) protocols

v. Percentage of adherence to safety precautions by employees working in diagnostics

vi. Mechanism of documenting and reporting for incidents, which could compromise the human safety, is being monitored

Assessment

	Compliance Requirements	Evidence
i.	Monitoring and Analysis	Document Review
	a. Percentage of reporting errors	Document Review
	b. Percentage of the re-dos in radiology and lab	Document Review
	c. Percentage of the reports correlating with clinical diagnosis	Document Review
ii.	Staff trained on SOPs for OH&S protocols	Document Review

iii.	Adherence to safety precautions by employees	Document Review
iv.	Recording and Reporting of incidents that could compromise the human safety	Document Review

Scoring

- If there is documented evidence that these factors are present and related activities are being monitored and reflected in the minutes of the CQI programme, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 101 Monitoring includes ALL invasive procedures

Survey Process

Review the documentation in the CQI committee minutes. Check to see if indicators such as the reporting of all adverse occurrences[25] such as return to operating room within 24 hours and re-admissions within 24 hours if related to invasive procedures is included.

Compliance Requirements

I. Evidence of monitoring and analysis of at least the following in percentages out of the total procedures for the period under review and its presentation in CQI committee:
  a. Percentage of the unplanned invasive procedures
  b. Percentage of rescheduling of the invasive procedures

ii. Percentage of the cases where the SOPs to prevent adverse events like wrong patient, wrong procedure, wrong site were practiced

iii. Percentage of cases who received prophylactic antibiotics within specified time frame

Assessment

	Compliance Requirements	Evidence
i.	Monitoring, analysis and record of **a.** Unplanned invasive procedures **b.** Rescheduling of the invasive procedures	Document Review
ii.	SOPs to prevent adverse events; wrong patient, wrong procedure, wrong site practiced	Document Review
iii.	Cases who received prophylactic antibiotics	Document Review

Scoring

- If there is documented evidence that monitoring of all the above requirements has been complied, then score as **fully met.**
- If any one of the above requirements is not complied, then score as **not met.**

25- An unplanned event with a negative consequence for the patient

Ind. 102 Monitoring include adverse Drug Events

Survey Process

Review the documentation in the committee minutes and check to see if there are references to adverse drug events such as allergic reactions, wrong dose, wrong drug, wrong patient, contraindications and similar issues and how these events have been managed.

Compliance Requirements

i. Monitoring and analysis of adverse drug events/ medication errors in the following aspects during the period under review and its presentation in CQI committee:

a. Prescribing errors
b. Errors in dispensing
c. Errors in medication administration

ii. Number of adverse drug reactions

iii. Number of medication charts with error prone abbreviation

iv. Number of patients receiving high risk medication developing adverse drug reactions

Assessment

	Compliance Requirements	Evidence
i.	Medication errors	Document Review
ii.	Number of ADRs	Document Review
iii.	Error prone abbreviation in medication Charts	Document Review
iv.	Number of patients on high risk medication developing ADRs	Document Review

Scoring

- If there is documented evidence that the above requirements have been monitored, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 103 Monitoring includes use of anaesthesia

Survey Process

Review the documentation in the committee minutes and observe for reporting adverse occurrence and adequate follow up from the anaesthetic services.
Compliance Requirements

Compliance Requirements

I. Evidence of monitoring and analysis of the following aspects in the use of anesthesia for the period under review and its presentation in CQI committee:

a. Percentage of modification of anesthesia plan
b. Percentage of unplanned ventilation following anesthesia
c. Percentage of adverse anesthesia events
d. Anesthesia related mortality rate

Assessment

	Compliance Requirements	Evidence
i.	Monitoring anesthesia services and record of analysis	Document Review

Scoring

- If there is documented evidence that the above aspects of anaesthesia services have been monitored and there has been adequate follow up, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 104 Monitoring includes use of blood and blood products

Survey Process

Review the documentation in the committee minutes and observe reporting of adverse occurrence and adequate follow up from the blood services.

Compliance Requirements

I. Evidence of monitoring and analysis of at least the following aspects in the use of blood and blood products for the period under review and its presentation in CQI committee:
   a. Percentage of transfusion reactions
   b. Percentage of wastage of blood and blood products
   c. Percentage of blood component usage
   d. Turnaround time for issuance of blood and blood products

Assessment

	Compliance Requirements	Evidence
i.	Monitoring and analysis of record	Document Review

Scoring

- If there is documented evidence that this has been monitored and adequate follow-up has occurred from the blood services, then score as **fully met.**
- If there is no evidence of monitoring and follow-up from the blood services, then score as **not met.**

Ind. 105 Monitoring includes availability and content of medical records

Survey Process

Review the documentation in the minutes of the committee meeting to observe references to the quality of medical records. Records should be standardized across the hospital with specific entries for each specialty service as required and entries for each shift, all procedures, vital signs and the status of the patient. Integrated notes in the medical record are preferred [26].

Compliance Requirements

Evidence of review and analysis of the following to monitor availability and content of medical records for the period under review and its presentation in CQI committee:

26- Integrated notes involve all careers writing sequentially in the progress notes so that doctors' nurses and paramedics all write in the same section of the notes.

i. Percentage of the medical records not having discharge summary
ii. Percentage of the medical records not having unique identifier
iii. Percentage of the medical records not having entries of all procedures, vital signs and the progress notes / status of the patient
iv. Percentage of medical records having incomplete or improper consent as applicable
v. Percentage of medical record that could not be produced
vi. Percentage of the medical record related to patient mortality
vii. Codification as per international classification of disease (ICD) optional

Assessment

	Compliance Requirements	Evidence
i.	Review and analysis of record	Document Review

Scoring

- If the above requirement is complied, then score as **fully met.**
- If any of the above requirement is not complied, then score as **not met.**

Standard 18.

Standard 18. CQI-3: Sentinel events are intensively analysed

Intent Statement
The sentinel events are defined as the untoward incidents and a patient safety event that results in death, permanent harm, or severe temporary harm. Sentinel events are debilitating to both patients and healthcare providers involved in the event. The standard requires the HCEs to define and enlist the possible sentinel events, analyze those intensively, if they occur with the intention to identify the root cause and institute such measures which eliminate or at least minimize their recurrence.

Ind. 106 The organization has defined and listed sentinel events

Survey Process
Review the written definition and the list of possible sentinel events that should include at the minimum; i. All unexpected deaths including infants, mothers and suicide, ii. Serious adverse patient events that caused, or could have caused, harm to the patient including return to the operating room within 24 hours, readmission within 24 hours, wrong-patient, wrong-site, wrong-procedure, medication error, iii. Patient violence against staff, iv. Violence against patients, v. Infant abduction, and vi. Switching of babies. Although not specifically required, it is good practice to also include "near misses".

Compliance Requirements
i. HCE has defined and listed the possible sentinel events
ii. The list of sentinel events available at all the patient care areas
iii. Staff awareness regarding the system to analyze the sentinel event and their responsibilities, in case an event occurs

Assessment

	Compliance Requirements	Evidence
i.	Defined list of Sentinel Events	Document Review
ii.	Availability of the list of Sentinel Events	Document Review
iii.	Awareness of staff regarding the system to analyze the sentinel event and their responsibilities, in case an event occurs	Interview

Scoring
- If the possible sentinel events are defined and listed and the list is available at all patient care areas, then score as **fully met.**
- If there is no list, or if it is not adequately comprehensive, then score as **not met.**

Ind. 107 Sentinel events are intensively analyzed when they occur

Survey Process

Ask for any documentation of intense analysis of any sentinel event that has occurred in the past 12 months. It is highly unlikely that none have occurred in the past 12 months and therefore, if none were reported, the surveyors should explore the reporting process. Although not specifically required, it is good practice to also include "near misses". Look to see if the system analyses the root cause and associated factors that contributed to the event.

Compliance Requirements

i. Record showing that the sentinel events were analyzed if any occurred

ii. System in place to analyze such events if it had occurred

Assessment

	Compliance Requirements	Evidence
i.	Record showing analysis of sentinel events when occurred	Document Review
ii.	System in place to analyze such events	Document Review
iii.	If no sentinel event occurred, record shows documented zero reporting for the said period	Document Review

Scoring

- If there was a reported sentinel event and it was intensively analysed, including corrective action to prevent or reduce the likelihood of reoccurrence, then score **fully met.** OR If no sentinel event was reported, but the survey team is comfortable that if one occurred it would be reported and analyzed, then also score as **fully met.**
- If there was a sentinel event, but there was either no analysis or the analysis was "superficial" such as limited to assigning blame to an individual, then score as **not met.**

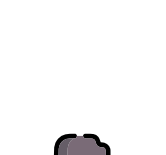
Functional Area: Responsibilities of Management

Outline:
Standards: 2 (19-20)
Indicators: 10 (108-117) (**8**+**2**)

Standard 19

Defined Responsibilities

- Mission Statement
- Strategic Plan
- Budget allocation
- Measurement of Performance
- Organogram
- Appointment of Senior Leaders
- Research & Quality Improvement Plans
- Legislations & Regulations
- Social & Community Responsibilities



Standard 20

Head of the Organization

- Qualifications & Experience

Core Elements of the Functional Area:
1. Mission Statement
2. Strategic Plan
3. Organogram
4. Social and Community Responsibilities
5. Research & Quality Improvement Plans

Standard 19.

The responsibilities of the management are defined

Intent Statement

The person/s responsible for governance have certain responsibilities which they discharge by themselves or through the management team. The responsibilities of the management, should therefore, be clearly defined and assigned. These responsibilities inter-alia include defining the mission statement, developing strategic and business plans, approval and provision of budget, develop the organogram with reporting liens, appoint adequate staff including senior leaders, ensure staff attendance, monitoring and measuring the performance, entering into contracts with the service providers for services which are not available on site, ensuring the deliverance of reports that are received after discharge of the patient, compliance with all legal provisions and meeting the social requirements.

The intent of this standard is to check that management is dynamically performing its duties.

Ind. 108 Those responsible for governance lay down the organization's mission statement

Survey Process

Review the hospital's mission statement and see whether the senior leadership, including those involved with the hospital's governance are involved in developing the same. See if the HCE policies support the mission statement including the effective and efficient allocation of resources particularly considering the human safety requirements. See if the mission is published for the information of the staff and patients. Interview staff to determine if they are aware of and support achievement of the mission.

Compliance Requirements

i. HCE mission statement is developed and displayed
ii. Evidence of involvement of senior management in developing the mission statement
iii. Awareness of the senior staff/management about mission statement

Assessment

	Compliance Requirements	Evidence
i.	HCE mission statement is displayed	Document Review
ii.	Evidence of involvement of senior management in developing the mission statement	Document Review
iii.	Awareness of the senior staff/management about mission statement	Interview

Scoring

- If the mission statement is documented and there is evidence of involving the senior leadership in developing the same and the senior staff is made aware about it then score as **fully met.**
- If either the mission statement is not documented or, there is no evidence of involving the senior leadership in developing the same or the staff is not aware about it then score as **not met.**

Ind. 109 Those responsible for governance lay down the strategic and operational plans

Survey Process

Review the strategic and operational plans and verify if the plans are commensurate with the hospital's mission and that the resources support accomplishing the plans.

Compliance Requirements

i. The management has developed the strategic and operational plans of the HCE

ii. Strategic and operational plans support accomplishing the mission statement of the HCE

Assessment

	Compliance Requirements	Evidence
i.	Strategic and operational plans of the HCE developed	Document Review
ii.	Strategic and operational plans support accomplishing the mission statement of the HCE	Document Review

Scoring

- If there are both strategic and operational plans and they are in accord with the hospital's mission and adequately supported by the senior management, then score as **fully met.**
- If there is a strategic plan but no operational plans yet to define how the strategy will be implemented, then score as **partially met.**
- If there is no strategic plan, then score as **not met.**

Ind. 110 Those responsible for governance approve the organization's budget and allocate the resources required to meet the organization's mission

Survey Process

Review the budget formulation process. Determine by review of the budget how it is approved and if it adequately supports the mission with resources.

Compliance Requirements

i. A document showing budget allocation and its approval process

ii. An official authorization in respect of the Board or Committee to approve the HCE's budget

Assessment

	Compliance Requirements	Evidence
i.	A document showing allocation of budget/ resources and its process	Document Review
ii.	An official authorization in respect of the Board or Committee to approve the HCE's budget	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 111 Those responsible for governance monitor and measure the performance of the organization against the stated mission

Survey Process

Review any documentation such as minutes of meetings of the governing body or the senior management of the hospital. There should be objective indicators that allow monitoring of progress toward meeting the hospital's strategic objectives that support its mission. The objective indicators to be included in the checklist for monitoring the progress may be selected from the performance assessment tool enforced by the PHC.

Compliance Requirements

I. Checklist containing objective indicators for monitoring the progress (may be selected from the performance assessment tool)

ii. Performance audit checklist reflecting corrective measures (if required) with the date, name and signatures etc. of responsible person who conducted it biannually at least

Assessment

	Compliance Requirements	Evidence
I.	Checklist containing objective indicators for monitoring the progress (selected from performance audit tool)	Document Review
ii.	Performance audit checklist reflecting corrective measures (if required) with the date, name and signatures etc. of responsible person who conducted it biannually at least	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 112 Those responsible for governance establish the organization's organogram

Survey Process

Review the organizational chart that displays the hospital's organizational structure depicting the reporting line.

Compliance Requirements

i. Organogram of the hospital established and displayed

Assessment

	Compliance Requirements	Evidence
i.	Organogram is displayed	Observation
ii.	Organogram depicts the hospital's organizational structure and reporting links	Interview

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 113 Those responsible for governance appoint the senior leaders in the organization

Survey Process

Review the process for appointment of the hospital's senior leaders. It must support the appointment of most appropriate people for all positions in terms of credentials and experience.
Compliance Requirements

Compliance Requirements

i. Evidence that senior leaders are appointed against all key positions in the HCEs
ii. Appointments on all leadership positions are appropriate in terms of credentials and experience

Assessment

	Compliance Requirements	Evidence
i.	Evidence that senior leaders in the HCEs are appointed by those responsible for governance	Document Review
ii.	Appointments against all leadership positions are appropriate in terms of credentials and experience	Document Review

Scoring

- If there is a clearly defined process for appointment of the senior leaders against key positions in the hospital and mechanism to ensure the attendance/ presence of the senior leaders /HODs during the duty hours, then score as **fully met.**
- If the process is limited to the appointment of hospital director only or if there is no mechanism to ensure presence of the senior leaders /HODs, then score as **partially met.**
- If there is no formal process, then score as **not met.**

Ind. 114 Those responsible for governance support research activities and quality improvement plans

Survey Process

Most of the category I HCEs are seats of learning and training attached with the teaching institutions approved for various undergraduate and post graduate courses for the medical, nursing and allied health professionals and would be undertaking research/s on various subjects. All research activities must be formally approved by the hospital management and/or the Ethical Review Committees as applicable. Review any report/s submitted to the governing body that document the results of the research activities including the process for approving the research protocols. Ideally, there should be an evidence regarding the governing body asking for more information or directing actions. The non-teaching HCEs, where formal / operational research is not undertaken, the reports of CQI programme and reviews by the CQI Committee may be considered as an alternative of research.

Compliance Requirements

i. Evidence that the senior management or the Ethical Review Committee approves the research activities/protocols (applicable to the HCEs attached with teaching institutions)

ii. Documentary evidence of research activities is available and that the senior management seeks and reviews the research report/s and issues directions or seeks more information for improvement (as applicable)

Assessment

	Compliance Requirements	Evidence
i.	Evidence that the senior management or the Ethical Review Committee approves the research activities/protocols (if applicable)	Document Review
ii.	Documentary evidence of research activities is available and that the senior management seeks and reviews the research report/s and issues directions or seeks more information for improvement as applicable	Document Review

Scoring

- If the above requirements are complied as applicable, then score as **fully met.**
- If none of the above requirements is not complied, then score as **not met.**

Ind. 115 The organization complies with the laid down and applicable legislations and regulations

Survey Process

The surveyors should be aware of the applicable laws and regulations that relate to hospitals in Punjab.[27] Ask to view the copies of applicable laws and regulations and determine if concerned staff members are aware of the laws and the legal / regulatory requirements their applicability for the hospital functioning.

Compliance Requirements

i. List of applicable Laws, Regulations & Rules is available

ii. Copies of laws, rules and regulations relevant to health, inter-alai relating to HWM, Blood Transfusion Safety, radiation safety, infection control, medication management, safety of buildings and physical environment etc.

iii. Awareness of the concerned staff about the relevant laws, rules, regulations and codes etc. and their applicability towards functioning of the hospital

Assessment

	Compliance Requirements	Evidence
I.	List of applicable Laws, Regulations & Rules is available	Document Review
ii.	Copies of all applicable laws, rules regulations and codes etc.	Document Review

27- Include inter-alia, the Punjab HWM Rules 2014, Punjab Hepatitis Prevention and Control Act, Fire and non-fire emergencies, Building safety Codes, PM&DC Ordinance, Ethics of Medical Practice, PNC Regulations, PHC Act 2010, Punjab Blood Safe Blood Transfusion Act, etc. as promulgated and amended from time to time.

iii.	Awareness of the concerned staff about the relevant laws, rules and regulations etc.	Interview

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 116 Those responsible for governance address the organization's social and community responsibilities

Survey Process

Look for documents that demonstrate that the hospital has evaluated its community's healthcare needs in terms of disease prevalence such as screening for hypertension, diabetes cancer etc. and making provisions for their treatment. Also look for any "out-reach" activities undertaken by the HCE for the purpose of providing health education to the masses about health issues and home based care provision for the needy.

Compliance Requirements

i. Record of'out-reach'activities such as:
a. Health education sessions to create awareness in the masses regarding health issues
b. Medical Camping with a goal to help those who cannot access the HCE
c. Any service to the compromised section of society
d. Providing patient care in case of emergency / disaster outreach care to needy people

Assessment

	Compliance Requirements	Evidence
i.	Record of 'out-reach' activities such as:	Document Review
	a. Health education sessions to create awareness regarding health issues	Document Review
	b. Medical Camping with a goal to help those who cannot access the HCE	Document Review
	c. Any service to the compromised section of society	Document Review
	d. Providing patient care in case of emergency / disaster outreach care to needy people	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If the above requirements are not complied, then score as **not met.**

Standard 20.

ROM-2: A suitably qualified and experienced individual heads the organization

Intent Statement

Healthcare establishments are highly complex organizations as they deal with the human lives mostly requiring some kind of emergency care that necessitate availability of almost all types of professionals in one way or other to provide services on 24/7 basis. The person heading the HCE is required to have in depth knowledge and experience to manage the entire spectrum of healthcare delivery systems that function under him, including the support functions related to organizational management and care provision. He needs to be conversant with the skills required for strategic planning, budgeting, human resource management, monitoring and measuring the performance, quality assurance / continuous improvement, Infection control, waste management systems, contract management and negotiation with the providers of services which are not available in house. The head of the HCE is also responsible for ensuring compliance with relevant statutory requirements, establishing and managing external linkages and meeting the social requirements etc. It is therefore imperative that an appropriately qualified and experienced person is appointed as head of the HCE.

The intent of this standard is to ensure that an appropriately qualified and experienced person having applied knowledge of the hospital management is appointed as head of the HCE.

Ind. 117 The individual designated to head the organization has requisite and appropriate administrative qualifications and experience

Survey Process

Review the job description of the hospital director and determine if the individual has the appropriate qualifications and experience to manage a complex multidimensional institution[29].

Compliance Requirements

I. Medical graduate with post graduate qualification in Hospital / Health Management and having at least 7 years' experience of hospital management.

OR

ii. A Clinical professional with post graduate qualification in the respective clinical field and assisted by a medial graduate with post-graduation in Hospital / Health Management and at least 5 years' experience of managerial aspects.

OR

iii. Other professionals with qualification in Management assisted by a medial graduate with 5 years' experience with post -graduation Hospital / Health Management for looking after technical aspects.

28- This would be additional / higher qualifications in the field of health / hospital management plus considerable experience and continuous professional development in the field of management. A doctor with an extensive clinical / medical CV and no management credentials would not be considered suitably qualified to run a major hospital.

Assessment

	Compliance Requirements	Evidence
i.	Medical graduate with post graduate qualification in Hospital / Health Management and having at least 7 - year experience of hospital management OR A Clinical professional with post graduate qualification in the respective clinical field and assisted by a medial graduate with post-graduation in Hospital / Health Management and at least 5-year experience of managerial aspects OR Other professional with qualification in Management assisted by a medical graduate with post-graduate qualification in Hospital / Health Management and at least 5 - year experience for looking after technical aspects	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Functional Area: Facility Management and Safety (FMS)

Outline:
Standards: 3 (21-23)
Indicators: 12 (118-129) (**4**+**8**)

Standard 21

Rules, Regulations & Laws

- Laws and Applicability to the hospital
- Updated Laws
- Legal Requirements
- Mechanism to Regularly Update

Standard 22

Equipment Management

- Plans for Equipment
- Selection Process
- Qualified Staff
- Periodic Preventive Maintenance

Standard 23

Fire & non-fire Emergencies

- Plans and Provisions
- Documented Safe Exit Plan
- Mock Drills
- Trained Staff

Core Elements of the Functional Area:
1. Facility management and safety related legislations
2. Plans and provisions for Fire and Non-fire safety
3. Training of the staff

Standard 21.

The organization is aware of and complies with the relevant laws, rules, regulations, bylaws, facility inspection requirements and associated codes applicable to the hospitals building and the relevant infrastructure

Intent Statement

Healthcare establishments have a complex building and infrastructure that are required to comply with multiple legal and regulatory requirements. These inter-alia include laws, bylaws, rules, regulations and facility inspection requirements under the relevant building and associated fire safety codes applicable to hospitals, lifts/ elevators, boilers, medical gases and handling of infected/contaminated and nuclear hospital waste etc. The hospitals/ HCEs are also responsible to ensure clean water supply, safe food, sanitation/environmental safety, ventilation, uninterrupted power supply, procurement of safe pharmaceuticals etc.

The intent of this standard is to validate that relevant building and associated codes applicable to hospitals/HCEs building and infrastructure are being complied in true spirit for ensuring safety of patients as well as the providers of the healthcare and the visitors. Undoubtedly, awareness of staff about the laws and their understanding of the applicability, is fundamental to implementation of statutory requirements.

Ind. 118 The management is conversant with the relevant laws and regulations and knows their applicability to the organization

Survey Process

Through observation and discussion with the concerned staff locate copies of the laws, regulations and associated codes relevant to the building and ask to show examples of their compliance. Examples should include fire safety requirements; lifts, elevators, medical gases and handling of infected/contaminated and nuclear hospital waste etc. There must be observable compliance with laws for at least clean water supply, sanitation/environmental safety, ventilation, uninterrupted power supply, safe food, procurement of safe pharmaceuticals. Regular and sustained compliance including management of all the above requirements, periodic preventive maintenance and effective contingency plans in the event of primary systems failure should be a routine.

Compliance Requirements

i. Copies of all relevant laws, rules and regulations related to building and fire safety, maintenance of lifts / elevators and handling of infected/contaminated and nuclear hospital waste, sanitation and environmental safety, ventilation, uninterrupted power supply, clean water supply, safe food and procurement of safe pharmaceuticals etc.

ii. Awareness of the relevant staff about the applicability of the regulatory requirements applicable to the functioning of the HCE and their respective role

Assessment

	Compliance Requirements	Evidence
i.	Copies of all relevant laws, rules and regulations related to building and fire safety, maintenance of lifts / elevators and handling of infected/contaminated and	Document Review

	nuclear hospital waste, sanitation/environmental safety, ventilation, uninterrupted power supply, clean water supply, safe food and procurement of safe pharmaceuticals etc.	
ii.	Awareness of the relevant staff about the applicability to the functioning of HCE and their respective role	Interview

Scoring

- If the management is conversant with the relevant laws and their applicability to the functioning of the HCE and their respective role, then score as **fully met.**
- If only 80% of the staff is conversant with the relevant laws and their applicability to the function of the HCE and their role, then score as **partially met.**
- If more than 20% of the staff is not conversant with the relevant laws and their applicability to the function of the HCE and their role, then score as **not met.**

Ind. 119 The management regularly updates any amendments in the prevailing laws of the land

Survey Process

Directly observe evidence of routinely updated laws and regulations.

Compliance Requirements

i. Process including an official assigned to keep updated copies of the prevailing laws and regulations

ii. Updated copies of the laws/regulations/rules available with the relevant staff

Assessment

	Compliance Requirements	Evidence
i.	Process including an official assigned to keep updated copies of the prevailing laws and regulations	Document Review
ii.	Updated copies of the laws/regulations/rules available with the relevant staff	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 120 The management ensures implementation of the current legal requirements

Survey Process

Check to see if documentation supports implementation of the current legal requirements and that this is confirmed with observable examples.

Compliance Requirements

I. Implementation is demonstrated by availability of valid certifications obtained after getting inspected for building safety, fire safety, radiation safety, safe blood transfusion, safe food, uninterrupted power supply and waste management etc.

ii. Evidence of regular/periodical fire safety drills and practicing the SOPs for radiation protection

Assessment

	Compliance Requirements	Evidence	
i.	Implementation demonstrated by valid certifications obtained after getting inspected for building safety, fire safety, lift safety, radiation safety, safe blood transfusion, safe food, uninterrupted power supply and waste management etc.	Document Review	
ii.	Evidence of regular/periodical fire safety drills and practicing the SOPs for radiation protection	Observation	Document Review

Scoring

- If there is evidence of compliance with all current legal requirements, then score as **fully met.**
- If there is more than 80% compliance, then score as **partially met.**
- If there is less than 80% compliance, then score as **not met.**

Ind. 121 There is a mechanism to regularly update certifications / registrations / licenses etc. as applicable

Survey Process

Directly observe and note the validity and currency of the range of compliance documents e.g. certifications and licenses etc. issued by the relevant authorities.

Compliance Requirements

i. Defined mechanism for regularly updating certifications and licenses etc.

ii. Range of valid/current certificates and licenses etc. available (PNRA license, service maintenance of lifts/elevators and boilers where applicable (mechanism and record) and log book of generators)

Assessment

	Compliance Requirements	Evidence	
i.	Defined mechanism to regularly update certifications and licenses etc.	**DR**	
ii.	Range of valid/current applicable certificates / licenses etc. available (PNRA license, service maintenance of lifts/elevators and boilers where applicable (mechanism and record) and log book of generators)	Document Review	Observation

Scoring

- If there is mechanism of regularly updating compliance documents and full range of valid/current certificates and licenses etc. are available, then score as **fully met.**
- If there is a mechanism of regularly updating compliance documents and full range of documents is available however, some are not current, then score as **partially met.**
- If there is there is no mechanism of regularly updating compliance documents or if there is incomplete range of compliance documents available, then score as **not met.**

Standard 22.

FMS-2: The organization has a programme for clinical and support service equipment management

Intent Statement

Availability and proper functioning clinical and support service equipment is fundamental for optimum healthcare delivery by the professionals at the HCEs. It is therefore imperative that the equipment required to provide the claimed and portrayed services is available and is properly functional at all times and whenever required. Indicators under this standard are therefore, designed to assess and confirm that the HCE/s have taken necessary steps for ensuring availability of all the required equipment and for keeping them functional up to the accuracy level as recommended by the OEM.

Ind. 122 The organization plans for equipment in accordance with its scope of services and strategic plan

Survey Process

Review any written plan that includes at least: 1. Acquisition, 2. Installation / Testing/ calibration 3. An inventory of ALL medical equipment in the hospital that includes evidence of a formal disposal (write-off) process. While visiting patient care areas, identify 5 pieces of medical equipment. Then ask for documentation that the equipment is listed on the hospital's inventory and that it was properly tested and calibrated when installed and the periodic preventive maintenance has been done on time. Check with the maintenance staff that they have the required training, service manuals and required tools, parts and consumables to deliver the required preventive maintenance and servicing etc. Check for valid sub-contracts for the service/ maintenance of equipment that is beyond the scope of in-house staff. Confirm that there is an adequate budget to support implementation of the procurement plan.

Compliance Requirements

i. List depicting equipment in accordance with the services being provided

ii. Written equipment plan includes at least the following:

- a. Written demand for equipment to meet the claimed services
- b. Installation /Testing/ calibration and periodic preventive maintenance
- c. An inventory of ALL medical equipment in the hospital and evidence of a formal disposal (write-off) process.

d. Adequately skilled staff

Assessment

	Compliance Requirements	Evidence
i.	List of equipment	Document Review
ii.	Written plan of installation /testing/ calibration and preventive maintenance	Document Review

Scoring

- If there is a plan (and evidence that it is resourced and implemented), then score as **fully met.**
- If there is a plan but it does not include the requirement for testing prior to use, or there are inadequate skills and resources for implementation, then score as **partially met.**
- If there is no medical equipment plan or if it does not include the requirement for testing prior to use or if there is no inventory of medical equipment, then score as **not met.**

Ind. 123 Equipment is selected by a collaborative process

Survey Process

Review the process for assessing needs and prioritizing the requests for new or replacement of medical equipment. There should be evidence that the appropriate department heads and 'end-users' participate in determining the best options and procurement priorities to deliver the claimed scope of services. There should preferably, be a dedicated equipment selection/ procurement team/committee comprising of the senior members from the clinical, financial, engineering and management departments. The variant may be NGOs or Public Sector departments having centralized procurement system with embedded arrangements in which it procures and provides equipment to peripheral set ups/HCEs.

Compliance Requirements

I. Requisition of the equipment by the respective department heads to deliver the claimed scope of services

ii. Preferably a notified equipment procurement team/committee comprising senior members from the clinical, financial, engineering and management departments

iii. Evidence that the appropriate department heads and 'end-users' participate in determining the best options and procurement priorities for equipment e.g. minutes of meetings signed and countersigned by all concerned

Assessment

	Compliance Requirements	Evidence
i.	Documented requisition for the equipment from the end user	Document Review
ii.	Notified equipment procurement team/committee	Document Review
iii.	Minutes of meetings signed by all concerned	Document Review

Scoring

- If there is a prioritized process for requesting new or replacement medical equipment and there is input from the appropriate department heads, then score as **fully met.**
- If there is a process, but no "meaningful" (surveyor judgment) input from the appropriate department heads, then score as **partially met.**
- If there is no process, or if the decision is left to a single individual, then score as **not met.**

Ind. 124 Qualified and trained personnel operate and maintain[29] the equipment

Survey Process

Review the job description of medical equipment maintenance personnel and their human resources file/s to verify that they have the required qualifications, knowledge and experience to operate and maintenance of the equipment. To determine if appropriate personnel operate the equipment correctly, look for documented training and any data (in the medical equipment department) that identifies "user error"[30].

29- Servicing and planned preventive maintenance can be outsourced to appropriately qualified technicians if required or a combination of in-house and outsourced maintenance and servicing would be fine.

30- Equipment failures due to incorrect use is common in hospitals

Compliance Requirements

I. Lists of equipment being maintained in house as well as outsourced with frequency of maintenance, is available

ii. Credentials of the staff operating and maintaining the equipment demonstrating that the qualification, experience and training of the personnel are appropriate as required

iii. Availability of a detailed MOU in case the maintenance of equipment is outsourced

Assessment

	Compliance Requirements	Evidence
i.	Lists of equipment being maintained in house as well as outsourced with frequency of maintenance, is available	Document Review
ii.	Credentials of the staff	Document Review
iii.	Availability of a detailed MOU	Document Review

Scoring

- If there is staff are adequately qualified and experienced and trained for all equipment within the scope of their ability and other equipment is serviced by reputable contractors, then score as **fully met.**
- If there is evidence of a system of planned preventive maintenance but there are concerns with the ability of the staff and the service contractors, then score as **partially met.**
- If there are inadequately qualified staff or subcontractors, then score as **not met.**

Ind. 125 Equipment is periodically inspected, serviced and calibrated to ensure their proper function. There is a documented operational and maintenance (preventive, breakdown and replacement) plan

Survey Process

There should be a written schedule that is based at least on original equipment manufacturers (OEM) guidelines /recommendations. The inspection, calibration (planned or if needed due to any reported error), and maintenance must be documented. The surveyors should review the documentation to see that scheduled preventive maintenance has been carried out on time. Also check with the maintenance staff that they have the required training, service manuals and required tools, parts and consumables for the required preventive maintenance and servicing regime. Check for valid sub-contracts to service the equipment that is beyond the scope of in-house engineers/staff. Confirm that there is an adequate budget to support implementation of the maintenance plan.

Compliance Requirements

i. Written schedule for Planned Preventive Maintenance (PPM) of medical equipment including calibration

ii. Documentary evidence in respect of implementation of scheduled/emergent inspection planned preventive maintenance and calibration of equipment

Assessment

	Compliance Requirements	Evidence
i.	Written schedule for Planned Preventive Maintenance (PPM)	Document Review

ii.	Documentary evidence of implementation of scheduled/emergent inspection planned preventive maintenance and calibration of equipment	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Standard 23.

FMS-3: The organization has plans for fire and non-fire emergencies within the facilities

Intent Statement

Hospitals/HCEs are complex organizations where different types of equipment and materials including power generators, volatile supplies, combustible chemicals, pharmaceuticals, linen, gases etc. are extensively used in the healthcare delivery processes. Besides multiple human resource working in the hospital and admitted patients, large number of public including attendants and relatives of the inmates visit a hospital any time round the clock. Such a complex but open environment has greater potential and chances of occurrence of fire and non-fire emergency incidents. Availability of documented plans and appropriate provisions to fight such incidents is therefore, direly needed in the hospitals.

Indicators under this standard therefore, are prescribed to assess and confirm that the HCEs has taken required steps for ensuring availability of the plans, required equipment and other provisions to handle such unforeseen incidents and that the HR is aware of the plans and well trained to use the equipment in case of such eventuality.

Ind. 126 The organization has plans and provisions for 1. early detection, 2. containment and 3. abatement of fire and non-fire emergencies

Survey Process

Review the plan to ensure that it addresses ALL the above 3 requirements. Then, by observation, reviewing the documentation and interviewing the staff, determine if ALL the requirements have been implemented[31].

Compliance Requirements

i. Written plan of fire and non-fire emergencies covering:
- a. Early detection
- b. Containment
- c. Abatement

ii. Availability of:
- a. Fire extinguishers
- b. Fire hose / water source
- c. Fire Alarm/Smoke Detectors

iii. Certificate from the relevant authority (Civil Defense or Rescue 1122) regarding fitness of equipment

Assessment

	Compliance Requirements	Evidence
i.	Written plan of fire and non-fire emergencies covering: a. Early detection b. Containment c. Abatement	Document Review

31- A threat matrix employed by SKMT is available at the PHC website as an example of industry standard

II.	Availability of: d. Fire extinguishers e. Fire hose / water source f. Fire Alarm/Smoke Detectors etc.	Document Review
III.	Certificate from the relevant authority in terms of fitness of the equipment	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 127 The organization has a documented safe exit (evacuation) plan in case of fire and non-fire emergencies

Survey Process

Review the "evacuation" plan that should be readily available and visibly displayed. There should also be documented evidence that the plan has been tested. It is not necessary that the hospital has actually evacuated all patients, but at least has conducted a "mock" evacuation of a single area or a department to verify that the plan would work in the event of an actual emergency. However, the plan should clearly define a "whole hospital" evacuation (as in an earthquake) plan, including defined alternate sites for the patients/staff and how to transport them. Training/orientation on these details should be included in the induction programme for new staff.

Compliance Requirements

i. Written and displayed plan for evacuation of the whole hospital including:
- a. Team formation
- b. Responsibilities
- c. Exit routes
- d. Assembly area
- e. Designated place/s for evacuated patients
- f. Training/orientation of all staff

ii. Emergency exit route signs

iii. Emergency exit points

Assessment

	Compliance Requirements	Evidence	
i.	Documented plan for evacuation of the whole hospital	Document Review	
ii.	Emergency exit route signs	Observation	
iii.	Emergency exit points	Observation	
iv.	Defined responsibilities and roles of the staff	Document Review	Interview

Scoring

- If there is a written facility evacuation plan, staff is aware of and trained in its use and it has been tested and emergency exit route signs and exit points are illuminated, then score as **fully met.**
- If there is a written evacuation plan and emergency exit route signs and exit points are marked, then score as **partially met.**
- If there is no documented plan, then score as **not met.**

Ind. 128 Mock drills are held at least once in a year

Survey Process

Look for documentation that "mock" drills have been done at least once in the past year. As for fire drills, the "mock" drills should have involved different areas and different shifts. The drills should be fully reported noting the staff involved, major observations and any subsequent changes to the system.

Compliance Requirements

i. Record of annual mock drill to confirm that
   a. Mock Drills have been held at least once in a year
   b. All departments/different areas have been subjected to mock drill in different shifts

ii. Interview staff to verify that the mock drills were actually conducted

Assessment

	Compliance Requirements	Evidence
I.	Record of annual mock drill	Document Review
ii.	Interview staff to verify that the mock drills were actually conducted	Interview

Scoring

- If the above requirements are complied, then score as **fully met.**
- IIf any of the above requirements is not complied, then score **not met.**

Ind. 129 Staff members are trained for their role in case of such emergencies

Survey Process

Look for documentation of the training that should include at least key personnel (personnel who have been assigned a specific duty in this regard) from every area and shift. They should be able to demonstrate awareness and ability to perform their own role and understanding of the role of others.
Compliance Requirements

Compliance Requirements

i. Documented evidence/ record of training all the staff members
ii. Staff awareness regarding their own role and understanding of the role others in case of emergencies

Assessment

	Compliance Requirements	Evidence
I.	Documented evidence/ record of training all the staff members	Document Review
ii.	Staff awareness regarding their own role and understanding of the role others in case of emergencies	Document Review

Scoring

- If there is documented evidence of training of key personnel in every area and shift, and staff is aware of their own role and about the role others in case of emergencies then score as **fully met.**
- If only a few (approximately 5) key personnel have not yet been trained, then score as **partially met.**
- If there has been no training or if more than 5 key personnel have not been trained or if the staff is not aware of their own role and about the role others in case of emergencies, then score as **not met.**

Functional Area: Human Resource Management (HRM)

Outline:
Standards: 4 (24-27)
Indicators: 14 (130-143) (**9**+**5**)

Standard 24

Orientation of staff members

- Staff oriented to organization's mission & goals
- Awareness about policies & procedures
- Awareness of rights & responsibilities
- Patient rights & responsibilities

Standard 25

Appraisal System

- Well documented appraisal system
- Awareness about the appraisal system
- Appraisal as Tool for development
- Appraisal at Pre-defined Intervals

Standard 26

Record Staff

- Personal Files
- Complete Information
- In-service training & education
- Employee evaluation

Standard 27

Evaluation of Credentials

- Patient Care without Supervision by Lawful Professionals
- Updated Record of Health Professionals

Core Elements of the Functional Area:

1. Organizational orientation Plan
2. Awareness of staff towards patient rights & responsibilities
3. Appraisal System
4. Personnel record of all staff

Standard 24.

HRM-1: The staff members joining the organization are oriented to the hospital environment, the institution, respective departments and their individual jobs

Intent Statement

All levels and categories of staff need to have clear understanding about the overall scope of services and policies of the HCE, the functioning and working of all the sections / departments and their role/s in respect of different departments and their own department / section. The Hospitals/HCEs are required to have an orientation programme for all the staff members so that they do not have any ambiguity about the overall complexity of the organizational and departmental functions as well as their individual roles.

A documented orientation plan covering different modules and aspects of the HCE and some senior person/s well trained to impart the orientation on regular basis is therefore, essential required in the HCE.

Indicators under this standard are therefore, designed to assess and confirm that the required steps ensuring availability of the written orientation plans/modules, trained staff to conduct orientation, required equipment and other provisions are taken by the HCEs. The indicators also assess that the HR is aware about the functions and policies of the HCE as well as their role/s in respect of other departments and their department and responds accordingly.

Ind. 130 The organization has a documented safe exit (evacuation) plan in case of fire and non-fire emergencies

Survey Process

The orientation of all should be in three parts: 1. Orientation to the hospital mission, goals and policies including subjects as fire and general safety, human safety, Infection prevention and control and the CQI etc., 2. Orientation to the assigned department/ section, and 3. Orientation to the specific job within that department. The content of each level of orientation should be written to ensure that whoever provides the orientation always covers the same topics with same details ensuring compliance to the following needs:

Compliance Requirements

i. Documented orientation guidelines about the HCE's mission, goals and policies including:

a. The hospital Departments / services related Policies, procedures, system of performance appraisal, patients' rights and responsibilities, human safety including fire and general safety, infection prevention and control, and CQI etc.

b. The assigned department/section

c. The specific job within the department

ii. Designated / trained staff and other provisions to conduct orientation of all staff members

Assessment

	Compliance Requirements	Evidence
I.	Documented orientation guidelines about the HCE's mission, goals and policies including: a. The hospital Departments / services related Policies, procedures, system of performance appraisal, patients' rights and responsibilities, human safety including fire and general safety, infection prevention and	Document Review

	control, and CQI etc. b. The assigned department/section c. The specific job within that department	
ii.	Staff awareness regarding their own role and understanding of the role others in case of emergencies	Document Review

Scoring

- If the above requirements are complied, then score **fully met.**
- If the orientation programmes covers all the three parts but what is to be covered is not clearly defined, then score as **partially met.**
- If there is no orientation programme, or it is not conducted at all then score as **not met.**

Ind. 131 Each staff member is made aware of relevant department/unit/service/programme policies and procedures

Survey Process

This would be part of the hospital wide and departmental orientation as in the preceding indicator and will be surveyed and scored accordingly. Review / observe the orientation programme and evidence of its implementation.

Compliance Requirements

I. Availability of an orientation material covering overall policies/procedures/guidelines/standing orders etc. of the HCE with the HR Department

ii. Detailed contents specific to each department for on job orientation of the staff related to their departmental functioning

iii. Evidence that orientation programme exists, the orientation is conducted and the relevant staff participated both in overall and departmental orientation

Assessment

	Compliance Requirements	Evidence
I.	Availability of an orientation material covering overall policies/procedures/guidelines/standing orders etc. of the HCE with the HR Department	Document Review
ii.	Detailed contents specific to each department for on job orientation of the staff related to their departmental functioning	Document Review
iii.	Evidence that orientation programme exists, the orientation is conducted and the relevant staff participated both in overall and departmental orientation	Document Review

Scoring

- If there is documented evidence that all staff have participated in an orientation process that includes induction to the policies and procedures for their work area, then score as **fully met..**

- If there is an adequate orientation programme and at least 80% of staff has been inducted, then score as **partially met**
- If there is an absence of an orientation programme or less than 80% of the staff has been involved in an orientation and induction programme, then score as **not met.**

Ind. 132 Each staff member is made aware of his/her rights and responsibilities

Survey Process

This indicator would require that each staff member has a written job description that defines his or her responsibilities. The staff member's rights should be detailed in the human resources employee manual or other documentation that is shared with the staff members.

Compliance Requirements

i. Written job descriptions of each staff member duly signed by him and the in charge /HOD/head of organization

ii. Staff rights well described/documented and communicated to each staff under their signatures

Assessment

	Compliance Requirements	Evidence
I.	Written job descriptions of each staff member duly signed by him and the in charge /HOD/head of organization	Document Review
ii.	Staff rights well described/documented and communicated to each staff under their signatures	Interview

Scoring

- If the above requirements are complied, then score **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Ind. 133 All employees are educated with regard to patients' rights and responsibilities.

Survey Process

It should either be part of the general hospital orientation, or there should be other document showing how ALL employees are educated about patients' rights and responsibilities.

Compliance Requirements

I. Patients' Rights/Responsibilities/Patient Charters are either included in the General Orientation or orientation of all employees is conducted on those as standalone document

ii. Evidence that all employees are educated about patients' rights and responsibilities

Assessment

	Compliance Requirements	Evidence
I.	Patients' Rights/Responsibilities/Patient Charters are either included in the General Orientation or Orientation of all employees is conducted on those as standalone document	Document Review
ii.	Evidence that all employees are educated about patients' rights and responsibilities	Interview

Scoring

- If there is documented evidence that all employees have been so educated on Patients' Rights/Responsibilities/Patient Charters, then score as **fully met.**
- If only direct caregivers/80% staff have been educated, then score as **partially met.**
- If there is no evidence that this education has been given, then score as **not met.**

Standard 25.

HRM-2: An appraisal system for evaluating the performance of the employees exists as an integral part of the human resource management process.

Intent Statement

Overall service provision at the HCEs is extensively dependent on the qualified, trained, licensed and motivated staff in all categories. The HCEs need to implement a comprehensive Performance Assessment System for evaluating performance of all the employees against the prescribed job description and the targets set by the organization and the staff need to be made aware of the assessment system. The HCEs' orientation programmes should include information about the performance assessment system being used for evaluation of the employees performance. The employees are required to understand that the are working in an environment where the ailing human beings are treated and in which their role is very crucial and hence their performance will be critically judged against the assigned role/job description.

Indicators under this standard therefore, are designed to assess and confirm that the HCE has taken the essentially required steps in this regard. These inter-alia include ensuring availability of a well-documented Performance Assessment System, orientation of the staff about the system, undertaking and documenting performance assessment in accordance with the pre-determined schedule and using the assessments as a tool for further development of the staff.

Ind. 134 A well-documented Performance Appraisal System exists in the organization

Survey Process

Review the appraisal system and particularly, for the evidence that it evaluates actual performance targets and not just administrative aspects. Review the human resources files of a random sample of employees (10) to determine if the appraisal is documented, it is carried out as per the pre-determined schedule, and includes evaluation of the employees' actual performance and incorporates plan for staff development to address any performance issues.

Compliance Requirements

I. A well-documented appraisal system that evaluates administrative factors as well as actual performance targets
ii. The systems provide the schedule for carrying out appraisals
iii. The appraisal system also incorporates the requirements for staff development to address any performance issues

Assessment

	Compliance Requirements	Evidence
I.	A well-documented appraisal system that evaluates administrative factors as well as actual performance targets	Document Review
ii.	The system provides the schedule for carrying out appraisals	Document Review
iii.	Appraisal system incorporates the requirements for staff development to address any performance issues	Document Review

Scoring

- If there is a documented appraisal system that includes evaluation of the employee's actual performance including the administrative factors as well as actual performance targets, provides the schedule for carrying out appraisals and incorporates the requirements for staff development to address any performance issues, then score as **fully met.**
- If there is a documented appraisal system but it only includes administrative issues and not actual performance evaluation, then score as **partially met.**
- If there is no documented appraisal system or if, it does do not contain all the above requirements, then score as **not met.**

Ind. 135 The employees are made aware of the performance appraisal system at the time of induction

Survey Process

This should be part of the initial orientation and there should be documented evidence, such as the employee's signature on the job description to confirm that the employee understood how their performance would be evaluated.

Compliance Requirements

i. Evidence that performance appraisal system was included in the Orientation programme /process at induction

Assessment

	Compliance Requirements	Evidence
I.	Evidence that performance appraisal system was included in the Orientation programme /process at induction	Document Review

Scoring

- If there is a clear system/process for the employee to understand how their performance will be evaluated, then score as **fully met.**
- If there is no system/process, then score as not met as **not met.**

Ind. 136 The appraisal system is used as a tool for further development

Survey Process

There should be documented evidence (when appropriate to the employee's appraisal) that the appraisal system is used as a tool for further development, such as more experience, more training, a different job assignment etc. This may not be required for every appraisal or every employee and will only be applicable if the appraisal indicated such need.

Compliance Requirements

i. Evidence that performance appraisal of an employee/s indicated further development in a particular aspect if so needed

ii. Evidence that the requirement indicated for further development was translated appropriately and the employee was imparted required training to achieve the performance level required for the job

Assessment

	Compliance Requirements	Evidence
I.	Evidence that performance appraisal of an employee indicated further development in a particular aspect if so needed	Document Review
ii.	Evidence that the requirement indicated for further development was translated appropriately and the employee was imparted required training to achieve the performance level required for the job	Document Review

Scoring

- The appraisal indicates the need for further development when needed and this is documented, then score as **fully met.**
- If the appraisal indicates the need for further development (surveyor judgment), but there is no documentation of this, then score as **not met.**

Ind. 137 Performance appraisal is carried out at pre-defined intervals and is documented

Survey Process

The hospital should have defined the frequency of performance appraisals. Customarily this is done within the first 3-4 months for a new employee joining the HCE and at least annually for ALL other employees. The surveyors should evaluate two things: 1. Has the hospital defined how often the performance appraisal would be carried out; and 2. What percent of employees have had their appraisal on time. It is common that a hospital has a schedule for periodic appraisals, but inconsistently follows it. Select a sample (10-15) human resources files and determine if the periodicity of appraisal was documented and if it was done "on time".

Compliance Requirements

i. Defined frequency of how often the appraisal would be carried out
ii. Percentage of employees who had their appraisal on time

Assessment

	Compliance Requirements	Evidence
I.	Defined frequency of how often the appraisal would be carried out	Document Review
ii.	Percentage of employees who had their appraisal on time	**Interview**

Scoring

- If the hospital has defined the frequency of employee performance appraisal and there is documented evidence that appraisal of more than 90 percent employees have been carried out timely, then score **fully met.**
- If the hospital has defined the frequency of employee appraisal, but the documentation shows that only up to 80 percent of employees had their appraisal on time, then scores **partially met.**
- If either the hospital does not have a schedule for periodic appraisal of employees' performance or if less than 80 percent of the employees had their appraisal "on time", then score as **not met.**

Standard 26.

HRM-3: There is a documented personnel record for each staff member

Intent Statement

Since provision of safe and quality healthcare is highly dependent on the qualified, trained, licensed and motivated credentialing of the medical, nursing and allied health staff is critically important. Validation of credentials and qualifications of the healthcare personnel is therefore, an important responsibility of the HCE's senior management to ensure that the staff is capable to deliver quality of healthcare in the healthcare organizations that meet the safety requirements. The overall objective of credentialing is to ensure that only qualified doctors, nurses and other professionals are employed/engaged to deliver services in the hospital, and that they practice/perform services competence with their scope of qualifications, experience, and licensure as applicable. This basic requirement is fulfilled by obtaining the required documents and verification of credentials at the time of induction and keeping in the personal record files which are updated as the individuals improve their qualification, experience, credentials and licensures.

Ind. 138 Personnel files are maintained in respect of ALL employees.

Survey Process

Randomly select 10-15 employees (either from a list of ALL employees, or by name of personnel identified during visits to hospital areas). Then determine if ALL have a human resource/personnel file.

Compliance Requirements

I. Make sure all employees have their personnel files, available in HR department
- a. Accurate
- b. Organized
- c. Complete in all respect
- d. Confidential

ii. Accessible on demand by authorized persons

Assessment

	Compliance Requirements	Evidence
I.	Make sure all employees have their personnel files, available in HR department a. Accurate b. Organized c. Complete in all respect d. Confidential	Document Review
ii.	Accessible on demand by authorized person	Document Review

Scoring

- If ALL have a human resources/personnel file, then score as **fully met.**
- If ANY file does not, then score as **not met.**

Ind. 139 The personnel files contain information regarding the employee's qualification, disciplinary background and health status

Survey Process

Randomly select 10-15 employees (either from a list of ALL employees, or by name of personnel identified during visits to hospital areas). Then determine if ALL have a human resource/personnel file that contain information regarding the employee's qualification, disciplinary background and health status etc..

Compliance Requirements

i. Existence of personal files of all the sampled HR

ii. The selected HR files contain the following:
- a. Qualification of the staff member
- b. Record of in service training
- c. Disciplinary back ground (record of any disciplinary action taken in the past)

iii. Record of health status of the employee

Assessment

	Compliance Requirements	Evidence
I.	Existence of personal files of all the sampled HR	Document Review
ii.	The selected HR files contain the following: i. Qualification of the staff member ii. Record of in service training iii. Disciplinary back ground (record of any disciplinary action taken in the past)	Document Review
iii.	Record of health status of the employee	Document Review

Scoring

- If ALL reviewed files have documented information regarding the employee's qualification, disciplinary background and health status, then score **fully met.**
- If any do not contain ALL the required information, then score as **not met.**

Ind. 140 ALL records of in-service training and education are contained in the personnel files

Survey Process

Review the same files as for previous indicator.

Compliance Requirements

I. Personal files contain the record of in-service training as relevant to the individual

Assessment

	Compliance Requirements	Evidence
I.	Personal files contain the record of in-service training as relevant to the individual	Document Review

Scoring

- If ALL the reviewed files contain documentation of in-service training / education (when relevant to the individual) and the employee's education, then score **fully met.**
- If any file does not document relevant in-service training, or does not document the employee's education, then score asas **not met.**

Ind. 141 Personal files contain results of ALL employee evaluations

Survey Process

This indicator relates to both the periodic appraisal and to any "ad hoc" evaluation (such as their involvement in an adverse event or disciplinary action etc.).

Compliance Requirements

I. Record confirming that periodic appraisal and any "ad hoc" evaluation if required was carried out and documented

Assessment

	Compliance Requirements	Evidence
I.	Record confirming that periodic appraisal and any "ad hoc" evaluation if required was carried out and documented	Document Review

Scoring

- If the reviewed human resource/personnel file contains the documentation of the periodic appraisal and the "ad hoc" appraisal if applicable, then score as **fully met.**
- If ANY file does not include the periodic appraisal or the "ad hoc" appraisal if applicable, then score as **not met.**

Standard 27.

HRM-3: There is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of medical professionals including physicians, nurses, pharmacists and others permitted to provide patient care without supervision

Intent Statement

Credentialing involves considering and establishing validity of the professional training, experience, and other requirements for hospital staff employment. It also involves obtaining and evaluating evidence of the qualifications of individual applicants/ employees. Credentialing primarily implies that each applicant/ potential employee, has a license that meets the criteria to authorizes him/her to practice provide services in the relevant field and meets the HCE's employment criteria. This requires verification from the primary source i.e. direct contact of the sources of credentialing, such as schools, residency programmes, and the licensing agencies /authorities to validate that statements of education, training, experience and other qualifications are legitimate. Currently the Higher Education Commission (HEC) or the chartered universities are is the main verifying agencies at the National and provincial levels.

Indicators under this standard are therefore, designed to assess and confirm that the HCEs have a system for collecting, verifying and evaluating the credentials (education, registration, training and experience as up dated from time to time) of the health personnel. This should include verification of credentials of all medical professionals including physicians, nurses, pharmacists and others permitted to provide patient care without supervision exists.

Ind. 142 Only medical professionals permitted by law, regulation and the hospital provide patient care without supervision

Survey Process

Look for documentation of the way the hospital validates the credentials of its medical staff to ensure that the professionals have appropriate and required documents and to demonstrate that they are legally permitted to provide healthcare to the patients. There should be a robust process to validate the accuracy of these documents as there are multiple examples of fraudulent "credentials" nationally as well as internationally. The hospital should have verified the documents with the primary source, such as the university or the training organization. Practitioners should be currently registered with their professional council or body.

Compliance Requirements

i. Defined process to validate the credentials of professionals
ii. Evidence of verification of documents from the primary source like regulatory councils etc.
iii. Valid registrations/certifications of the practitioners with the professional council or body

Assessment

	Compliance Requirements	Evidence
I.	Defined process to validate the credentials	Document Review
ii.	Evidence of verification of the documents from the primary source	Document Review

iii.	Valid registrations/ certifications of the practitioners with the professional councils or bodies	Document Review

Scoring

- If there is a clearly defined process to validate the "credentials" of ALL staff members, then score as **fully met.**
- Since this is an important legal issue as well as a patient safety issue, if there is no recognized process to validate the "credentials", then score as **not met.**

Ind. 143 The 1. Education, 2. Registration, 3. Training and 4. Experience of the identified health professionals is documented and updated periodically

Survey Process

Randomly select the human resource/personnel files of approximately 10 members of the medical and other staff. Review these files to determine if the 4 required elements i.e. education, registration, training and experience of the health professionals are present and updated.

Compliance Requirements

I. All the reviewed human resource/personnel files contain documentation regarding the education, registration, training and experience of the health care professionals

ii. Documentation is updated

Assessment

	Compliance Requirements	Evidence
I.	Documentation regarding the education, registration, training and experience of all health care professionals in the HR files	Document Review
ii.	Document is updated	Document Review

Scoring

- If ALL reviewed files contain documentation of education, registration, training and experience of the identified medical professional, then score as **fully met.**
- Since this is an important issue, if ANY file does not contain ALL the required information, then score as **not met.**

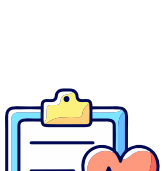
Functional Area: Information Management System (IMS)

Outline:
Standards: 3 (28-30)
Indicators: 19 (144-162) (**13**+**6**)

Standard 28

Medical Record

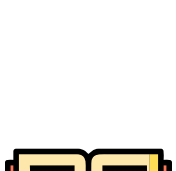
- Unique Identifier
- Authorized Person
- MR Dated, signed & Timed
- Author Identifiable



Standard 29

Continuity of Care

- MR in Chronological Account
- Completeness of MR
- Performed Procedures
- Transfer Records
- Discharge Note/Summary
- Death Certificate
- Clinical Autopsy Certificate



Standard 30

Review of Medical Record

- Access & confidentiality of MR
- Periodical Review
- Statistical Principles Based
- Identified Care Providers
- Completeness
- Active and discharged
- Deficiency in Medical Record
- Corrective and Preventive Measures

Core Elements of the Functional Area:

1. Management of medical record
2. Scrutiny of the medical record
3. Identification of deficiencies in the medical record

Standard 28.

IMS-1: The organization has a complete and accurate medical record for every patient

Intent Statement

Credentialing involves considering and establishing validity of the professional training, experience, and other requirements for hospital staff employment. It also involves obtaining and evaluating evidence of the qualifications of individual applicants/ employees. Credentialing primarily implies that each applicant/ potential employee, has a license that meets the criteria to authorizes him/her to practice provide services in the relevant field and meets the HCE's employment criteria. This requires verification from the primary source i.e. direct contact of the sources of credentialing, such as schools, residency programmes, and the licensing agencies /authorities to validate that statements of education, training, experience and other qualifications are legitimate. Currently the Higher Education Commission (HEC) or the chartered universities are is the main verifying agencies at the National and provincial levels.

Indicators under this standard are therefore, designed to assess and confirm that the HCEs have a system for collecting, verifying and evaluating the credentials (education, registration, training and experience as up dated from time to time) of the health personnel. This should include verification of credentials of all medical professionals including physicians, nurses, pharmacists and others permitted to provide patient care without supervision exists.

Ind. 144 Every medical record has a unique identifier [32]

Survey Process

Identify that each medical record has a unique identifier. The important issue is that there may be more than one record for a patient and there would be possibility that the information such as laboratory or pathology results might be placed into the wrong patient's medical record. It is therefore, important to ensure that medical record of each patient has a single unique identifier and that it can be retrieved with the help of identification code.

Compliance Requirements

Compliance Requirements

I. Use of unique identifier for each patient's medical record in practice (Like OPD, IPD, ED and in Diagnostics)

Assessment

	Compliance Requirements	Evidence
I.	Use of unique identifier for each patient's medical record in practice	Document Review

Scoring

- If there is a clear mechanism of assigning unique identifier to positively identify each patient's medical record, then score as **fully met.** OR if there is the possibility that an individual patient has more than one record, but there is a system to identify this and consolidate the various records, then also score as **fully met.**
- If there is no mechanism of assigning unique identifier to each medical record and if there is no mechanism to consolidate record of a patient in case there are more than one records, then score as **not met.**

32 -An alpha/numeric system that gives each patient their own code number

Ind. 145 Organizational policy identifies those authorized to make entries in the medical record

Survey Process

Review the policy and then during review of medical records for any of the previous reasons, confirm that only authorized individuals have made entries into the medical record.

Compliance Requirements

i. Written SOP as to who can make entries in the medical record
ii. Authorization on the prescribed format

Assessment

	Compliance Requirements	Evidence
I.	Written SOP as to who can make entries in the medical record	Document Review
ii.	Authorization on the prescribed format	Document Review

Scoring

- If ALL entries are made by authorized persons, then score as **fully met.**
- If there are any entries by unauthorized persons, then score as **not met.**

Ind. 146 Every medical record entry is dated and timed

Survey Process

This is a difficult indicator to achieve since the "timing" of ALL entries may be difficult to be recorded. Focus attention on timing of medical orders and any entries in ICU's/HDUs which must be dated and timed. This can be evaluated during the review of the previously selected records.
Compliance Requirements

Compliance Requirements

i. All entries in the medical record are dated and timed

Assessment

	Compliance Requirements	Evidence
I.	All entries in the medical record are dated and timed	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If only 80% entries in the medical records in the ICUs, HDUs and of other areas are dated and timed, then score as **partially met.**
- If date and time of the entries in the ICUs and HDUs medical record is missing or compliance for other areas is less than 80%, then score as **not met.**

Ind. 147 The author of the entry can be identified

Survey Process

During review of the previous medical records verify that ALL entries can be identified by both the individual name and their specialty (doctor, nurse, etc.).

Compliance Requirements

i. Name, signatures and preferably stamp in case of hard copies/manual record
ii. Name and digital stamping in case of EMR

Assessment

	Compliance Requirements	Evidence	
I.	Name, signatures and stamp in case of hard copies/manual record	Document Review	
ii.	Name and digital stamping in case of EMR	Observation	Document Review

Scoring

- If ALL entries can be identified by name and title, then score as **fully met.**
- If less than 2/up to 2 of 10 entries cannot be identified, then score as **partially met.**
- If 3 or more entries cannot be identified, then score as **not met.**

Ind. 148 The record provides an up-to-date and chronological account of patient care

Survey Process

Review the medical record to determine that it provides an up-to-date care and treatment provided in a chorological order. Ideally the pathways for all patients should be adequately documented using a standard coding system of disease classification (International Classification of Diseases, 10th/as Revised from time to time). Check the systems of records storage to ensure they are in good order and stored for a period in compliance with the statute of limitations Act 1908[33] or the relevant statutory instructions issued by the competent forum from time to time.

Compliance Requirements

I. Up-to-date medical record depicting an account of care /treatment provided in a chorological order and date wise

ii. Systems for storage of records in good order and stored for a period in compliance with the provisions of the Limitations Act 1908 or the relevant statutory instructions issued by the competent forum from time to time.

33- The Limitation Act 1908 requires records be stored for 12 years. Some hospitals in Pakistan have electronically stored records with capacity for analytical reporting and research. http://www.vakilno1.com/saarclaw/pakistan/limitationact/limitationact.htm

Assessment

	Compliance Requirements	Evidence
I.	All patients' medical record maintained in a chronological order	Document Review
ii.	Storage of records in good order and for a period in compliance with the statutory provisions instructions	Document Review

Scoring

- If the above requirements are complied, then score as **fully met.**
- If any of the above requirements is not complied, then score as **not met.**

Standard 29.

IMS-2: The medical record reflects continuity of care

Intent Statement
Doctors generally prefer maintaining Electronic Medical Records (EMRs) as it provides a quick access to the previous records and facilitates further treatment/management. An EMR should include medical history, results of any examinations and final decisions pertaining to a course of treatment. The document serves as the reasoning behind why medical treatment was administered in a certain manner, thus ensuring continuity.

In many situations, EMRs are legal documents that protect both the caregiver and the patient from legal proceedings. If treatment is ineffective for whatever reason and the patient feels that more could have been done for the care provision, the EMR provides insight into the doctor's thoughts and supports his or her conclusion. Conversely, if the doctor mismanaged the information, the document would help a patient garner proper compensation for any mismanagement or misuse of resources on the part of the doctor. An EMR is essential for superior medical documentation and care.

Ind. 149 The medical record contains information regarding reasons for admission, diagnosis and plan of care

Survey Process
Review 10 medical records (they can be the same record as for previous Indicators) to determine if the reason for 1. Admission, 2. The provisional diagnosis, and 3. The plan of care is documented. This is then scored on the cumulative findings for ALL the records reviewed.
Compliance Requirements

Compliance Requirements

i. Record clearly showing:
- a. Reasons for admission
- b. Provisional/Final Diagnosis
- c. Care Plan.

Assessment

	Compliance Requirements	Evidence
I.	Record clearly showing: a. Reasons for admission b. Provisional/Final Diagnosis c. Care Plan	Document Review

Scoring
- If ALL the required 3 elements above are documented in ALL the records, then score as **fully met.**
- If any of the 3 elements is missing in any record, then score as **not met.**

Ind. 150 Operative and other procedures performed are incorporated in the medical record

Survey Process

Review 10 records of patients who underwent surgery or an invasive procedure to verify that the record adequately documents the procedure performed. The documentation should include at least: 1. The name of the service provider, 2. The procedure undertaken, 3. The findings, 4. Any specimens removed, and 5. The patient's condition at the conclusion of the surgery/procedure.

Compliance Requirements

i. i. The medical records of all operations and procedures document the following details:
- a. The name of the service provider
- b. The procedure performed
- c. The findings
- d. Any specimens removed
- e. The patient's condition at the conclusion of the surgery/procedure

Assessment

	Compliance Requirements	Evidence
I.	The medical records of all operations and procedures document the following details: a. The name of the service provider b. The procedure performed c. The findings d. Any specimens removed e. The patient's condition at the conclusion of the surgery/procedure	Document Review

Scoring

- If ALL medical records have documentation of the above 5 requirements of the surgery/procedure, then score as **fully met.**
- If ANY medical records do not have ALL the 5 requirements documented, then score as **not met.**

Ind. 151 When a patient is transferred to another hospital, the medical record contains the essential information

Survey Process

Ask for the medical record of 3 or more patients who were transferred to another hospital. Check the forwarded essential information to determine if it includes the results of any diagnostic investigations and any treatments rendered prior to transfer and the clinical status of the patient.

Compliance Requirements

i. The medical records of patients transferred to another, HCE should have:
- a. Date of transfer,
- b. Reason for the transfer and
- c. Name of the receiving hospital

d. Investigations conducted and the reports
e. Treatment rendered
f. Any other details e.g. arrangements for care provision during transfer if so needed

ii. Transfer/referral slip/s having detailed information about the patient's condition for the receiving hospital to facilitate further treatment

Assessment

	Compliance Requirements	Evidence
i.	The medical records of patients transferred to another, HCE should have: a. Date of transfer, b. Reason for the transfer and c. Name of the receiving hospital d. Investigations conducted and the reports e. Treatment rendered f. Any instructions /arrangements for care provision during transfer if so needed	Document Review
ii.	Transfer/referral slip/s having detailed information about the patient's condition to facilitate further treatment at the receiving hospital	Document Review

Scoring

- If the medical record documents the date of transfer, the reason for transfer, treatment rendered and the name of the receiving hospital, then score as **fully met.**
- If the medical record fails to document any of the above requirements, then score as **not met.**

Ind. 152 The medical record contains a copy of the discharge note duly signed by appropriate and qualified personnel

Survey Process

Review 10 medical records of discharged patients. The discharge summary duly signed by the appropriate/ authorized personnel should include at least the following: 1. The reason for admission, 2. Significant diagnostic investigation results, 3. Any procedures or other treatments provided, 4. The patient's response to treatment, 5. Any discharge medications, and 6. Follow-up instructions.

Compliance Requirements

i. The reason for admission
ii. Results of significant diagnostic investigations
iii. Any procedure/s performed or other treatments rendered
iv. The patient's response to treatment
v. Any medications prescribed on discharge
vi. Follow-up instructions

Assessment

	Compliance Requirements	Evidence
i.	The reason for admission	Document Review

ii.	Results of significant diagnostic investigations	Document Review
iii.	Any procedure/s performed or other treatments rendered	Document Review
iv.	The patient's response to treatment	Document Review
v.	Any medications prescribed on discharge	Document Review
vi.	Follow-up instructions	Document Review

Scoring

- If ALL discharge summaries include ALL the 6 requirements above, then score as **fully met.**
- Since this is a significant continuity of care issue, if ANY discharge summary does not include ALL the 6 requirements, then score as **not met.**

Ind. 153 In the case of death, the medical record contains a copy of the death certificate indicating the cause, date and time of death

Survey Process

Ask for 2-3 records of patients who have died. Review these records to verify that they contain a copy of the death certificate that includes the cause, date and time of death.

Compliance Requirements

i. Signed death certificate in the record having information regarding, cause, date and time of death

Assessment

	Compliance Requirements	Evidence
i.	Signed death certificate in the record having information regarding cause, date and time of death	Document Review

Scoring

- If ALL death records include the cause, date and time of death, then score as **fully met.**
- If any do not include ALL the requirements (cause, date and time of death), then score as **not met.**

Ind. 154 Whenever a clinical autopsy is carried out, the medical record contains a copy of the report of the same

Survey Process

Clinical Autopsies are performed to establish the nature of the disease which led to death, when ante-mortem efforts have failed and to study pathology of the disease which has caused death, even when the diagnosis has been established before death. A clinical autopsy may only be performed when it is certain that the death does not have medico legal implications. The medical record of medico legal cases should however, be clearly so marked. Ask for 2-4 medical records of patients who had an autopsy, verify that the final report is kept in the medical record.

Compliance Requirements

I. The medical record contains a copy of the autopsy report, which:

a. States tenability/correlation of the cause of death with the clinical record (medical case sheet) of present and past illness
b. Requisition from the concerned clinician mentioning specific reasons/ doubts, that necessitated determination of clinico-pathological correlation and better understanding for future
c. Certificate by the HCE in charge whether the death is medico-legal or not before ordering the clinical autopsy and evidence that this confirmation was provided to the prosector[34] .
d. Autopsy performed as a compliance of written order to the prosector by the hospital administrator along with consent obtained from the legal next of kin, explaining the extent of autopsy and collection of material for any required investigation

Assessment

	Compliance Requirements	Evidence
i.	The medical record contains a copy of the clinical autopsy report as applicable which: **a.** States tenability/correlation of the cause of death with the clinical record (medical case sheet) of present and past illness **b.** Requisition from the concerned clinician mentioning specific reasons that necessitating need for determination of clinico-pathological correlation and better understanding for future **c.** Certificate by the HCE in charge whether the death is medico-legal or not before ordering the clinical autopsy and evidence that this confirmation was provided to the prosector . **d.** Autopsy performed as a compliance of written order to the prosector by the hospital administrator along with consent obtained from the legal next of kin, explaining the extent of autopsy and collection of material for any required investigation	Document Review

Scoring

- If ALL the reviewed medical records contain the final clinical autopsy report as applicable, then score as **fully met.**
- If any reviewed medical records do not have the final report if applicable, then score as as **not met.**
- In cases where autopsy was not requested/ conducted will be marked as **Not Applicable**.

Ind. 155 Care providers have access to current and past medical records

Survey Process

Ask for the names of 5 patients who were previously discharged their records for review. Inquire form the relevant professionals/staff for their experience regarding the access whenever they request such records.

Compliance Requirements

i. Documentary evidence of existence of Policy/SOP on access of medical record
ii. Record asked for by the surveyors is provided

34- A person who dissects dead bodies for examination or anatomical demonstration.

Scoring

- If there is a documented policy /SOP regarding access to the medical record and all the requested records are available (brought to the surveyor), then score as **fully met.**
- If only 4 of the 5 (80%) medical records are available, then score as **partially met.**
- If only 3 medical records are available, then score as **not met.**.

Standard 30.

IMS-3: The organization regularly carries out review of medical records

Intent Statement

Medical records, both manual and electronic, contain important information about the patient which is entered by the healthcare providers. Since the medical record is an important tool of communication amongst the members of healthcare team, it is therefore, imperative that the record of the admitted as well as past patients is periodically reviewed by the authorized professionals. The Electronic Medical Records (EMRs)/Computerized Medical Records are implemented with the intentions to improve the quality of care provided to patients. Through periodically reviewing the representative sample of the records, the authorized care providers and health professionals can ascertain the timeliness, legibility and completeness of the active and discharged patient's medical records. The deficiencies in the records identified and documented enable the concerned professionals implement corrective actions for preventing errors in future and improving patient care.

Ind. 156 The medical records are reviewed periodically

Survey Process

There should be a documented policy or SOPs defining the hospital process for periodic review of the medical records. The documented SOPs should also define the frequency of this review that should occur at least on quarterly basis.

Compliance Requirements

I. Document defining the policy /SOPs and frequency regarding review of the medical record on quarterly basis

ii. Evidence that policy to review the medical record is implemented accordingly

Assessment

	Compliance Requirements	Evidence
i.	Document defining the policy /SOPs and frequency regarding review of the medical record	Document Review
ii.	Evidence that policy to review the medical record is implemented accordingly	Document Review

Scoring

- If the hospital has a medical record review process and a schedule and evidence that it has occurred at least on quarterly basis, then score as **fully met.**
- If the hospital has a medical record review process, but it has only occurred twice in the past 12 months, then score as **partially met**.
- If the hospital does not have a medical record review process, or it has never been implemented (no meetings or documentation), then score as **not met.**

Ind. 157 The review uses a representative sample based on the scope of services and statistical principles

Survey Process

Check the documentation of the review to determine if the sample was reflective of the hospital's services and staff. There should be evidence that the hospital has defined the sample size keeping in view the scope of services provided in the hospital.

Compliance Requirements

i. Check policy/SOP to determine sample size

ii. Evidence to the effect that reviewed record /review report reflects the sample is in accordance with the SOPs and the hospital's services

Assessment

	Compliance Requirements	Evidence
i.	Documented policy/ SOPs to determine sample size	Document Review
ii.	Evidence that reviewed record reflects the sample size as per SOPs	Document Review

Scoring

- If there is evidence that a representative sample (covering the scope of the hospital's services and its staff) is reviewed and that the sample selected was representative of all the clinical departments, then score as **fully met.**
- If the sample is not representative as per policy/ SOPs or reflective of the scope of services, but medical review record shows that the sample selected was representative of 80 % of the clinical departments, then score as **partially met.**
- If there is no review, then score as **not met.**

Ind. 158 The review is conducted by identified/ authorized care providers and health professionals

Survey Process

Look for documented evidence that the review was conducted by professionals from disciplines that are authorized to make entries into the medical record. The review should not be done only by personnel responsible for keeping /maintenance of the medical records.

Compliance Requirements

Compliance Requirements

i. Document / authorization of the professionals for the review of the medical record from the disciplines that are authorized to make entries into the medical record

ii. Evidence to the effect that review was undertaken by the authorized professionals; names, date and signatures on the review report

Assessment

	Compliance Requirements	Evidence
i.	Document / authorization of the professionals for the review of the medical record	Document Review
ii.	Evidence to the effect that review was undertaken by the authorized professionals; names, date and signatures on the review report	Document Review

Scoring

- If there is documented authorization and the evidence that the review was done by members of disciplines authorized to make entries into the medical record, then score as **fully met.**
- If the review does not include representatives of ALL disciplines who are authorized to make entries into the medical record, then score as **partially met.**
- If the review is not done or it is done only by medical records personnel, then score as **not met.**

Ind. 159 The review focuses on the timeliness, legibility and completeness of the medical records

Survey Process

Analyze documentation of the review to verify that it includes timeliness, legibility and completeness of the medical records.

Compliance Requirements

i. Evidence to the effect that the review verifies/ focuses on the following:
   a. Timeliness
   b. Legibility
   c. Completeness of the medical records

Assessment

	Compliance Requirements	Evidence
i.	Evidence to the effect that the review verifies/ focuses on the following: d. Timeliness e. Legibility f. Completeness of the medical records	Document Review

Scoring

- If there is documented evidence that the record was reviewed for timeliness, legibility and completeness of the medical records, then score as **fully met.**
- If the review does not include timeliness, legibility and completeness, then score as **not met.**

Ind. 160 The review process includes records of both active (current) and discharged patients

Survey Process

Check the documentation of the review process to verify that both "open" and "closed" records were included in the review. An "open" or active or current record is that of a patient currently hospitalized whereas a "closed" record refers to medical record of a patient who has been discharged.

Compliance Requirements

I. Evidence that both "open" and "closed" records were reviewed

Assessment

	Compliance Requirements	Evidence
i.	Evidence that both "open" and "closed" records were reviewed	Document Review

Scoring

- If the review includes both "open" and "closed" records, then score as **fully met.**
- If the review does not include both "open" and "closed" records, then score as **not met.**

Ind. 161 The review identifies, and documents any deficiencies in the record

Survey Process

Check the minutes or other documents that demonstrate the findings of the review report, including deficiencies identified. It is highly unlikely that the hospital's review has not identified any problems with medical record documentation.

Compliance Requirements

I. Deficiencies pointed out and documented accordingly

Assessment

	Compliance Requirements	Evidence
i.	Deficiencies identified and documented	Document Review

Scoring

- If the documentation includes identification of any deficiencies, then score as **fully met.**
- If the review does not document identification of any deficiencies, then score as **not met.**

Ind. 162 Appropriate corrective and preventive measures undertaken in the light of identified deficiencies are documented

Survey Process

Check the minutes/ documentation to confirm that corrective and preventive measures were taken in the light of deficiencies identified in the review of the medical record.

Compliance Requirements

i. Documentation to the effect that corrective and preventive actions were suggested

ii. Evidence that corrective and preventive measures / actions were taken

Assessment

	Compliance Requirements	Evidence
i.	Evidence to the effect of actions taken as corrective and preventive measures were suggested and undertaken	Document Review

Scoring

- If the minutes document corrective action when indicated, then score as **fully met.**
- If the minutes do not document any corrective action when indicated, then score as **not met.**

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Dr. Muhammad Saqib Aziz
Chief executive Officer
Punjab Healthcare Commission

Punjab
Healthcare Commission

We value the input and feedback of our stakeholders and community. If you have any queries or suggestions, please contact us at **info@phc.org.pk.**

Thank you
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MSDS

Minimum Service Delivery Standards for HOSPITALS

2024

Punjab Healthcare Commission

185 Ahmad Block, New Garden Town Lahore - 54000

0092 42 99333 161-168 0092 42 99333 169

www.phc.org.pk info@phc.org.pk

PunjabHealthcareCommission PHC_punjab phcofficialpk

Punjab Healthcare Commission 0306 0843500

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